

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS S0

Product Name

## PRIMAL SPORTS NUTRITION HYPER SHRED

(Capsules)

Each PRIMAL HYPER SHRED capsule contains:		% NRV*
Sinetrol® xpurC	315,00 mg	
[Citrus and guarana extracts, providing flavones from Naringin and Hesperidin (>40 %) and caffeine 3.3-4 %]		
<i>Ilex paraguariensis</i> (Yerba Mate)	250,00 mg	
[Leaf; 25,00 mg of a 10:1 extract]		
Total Caffeine	150,00 mg	
Caffeine anhydrous	137,40 mg	
Sinetrol® xpurC (3.3-4 %)	12,60 mg	
<i>Aframomum melegueta</i> (Grains of Paradise)	150,00 mg	
[xxxxx; 15,00 mg of a 10:1 extract]		
<i>Juniperus communis</i> (Juniper Berry)	12,50 mg	
[Fruit powder]		
L-Theanine	75,00 mg	
Chromium (as Chromium Polynicotinate)	50,00 µg	143 %
Sugar free		
*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).		

#### Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

#### Read all of this leaflet carefully because it contains important information for you.

PRIMAL HYPER SHRED is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use PRIMAL HYPER SHRED carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PRIMAL HYPER SHRED with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

#### What is in this leaflet:

- What PRIMAL HYPER SHRED is and what it is used for.
- What you need to know before you use PRIMAL HYPER SHRED.
- How to use PRIMAL HYPER SHRED.
- Possible side effects.
- How to store PRIMAL HYPER SHRED.
- Contents of the pack and other information.

#### 1. What PRIMAL HYPER SHRED is and what it is used for

Indicated as an aid to a weight management programme, in conjunction with a balanced diet and exercise program.

#### 2. What you need to know before you use PRIMAL HYPER SHRED

##### Do not use PRIMAL HYPER SHRED:

- If you have a hypersensitivity to any of the ingredients or the excipients listed in 6.1.
- Consult a health care provider prior to use if you are pregnant or breastfeeding.
- Consult a healthcare provider prior to use if you have a kidney disorder.
- Consult a healthcare provider prior to use if you are taking other diuretics.
- Not recommended for use in children under the age of 18 years.

#### Warnings and precautions

Consult with a healthcare provider prior to using PRIMAL HYPER SHRED, especially if you have a medical condition.

#### Use PRIMAL HYPER SHRED with caution:

- Consult a healthcare provider prior to use if you are pregnant, breastfeeding or have a kidney disorder.
- Consult a healthcare provider prior to use if you are taking other diuretics.
- CONTAINS CAFFEINE. Not suitable for children under the age of 18 years.
- Not intended as a substitute for sleep.
- Hypertension, glaucoma and/or detrusor instability (overactive bladder syndrome).
- Consult a health care provider prior to use if you have high blood pressure, glaucoma, and/or detrusor instability (overactive bladder syndrome). The caffeine content may increase high blood pressure, increase intraocular pressure, and/or worsen symptoms of incontinence (such as urinary frequency and urgency).
- May reduce blood flow to the heart muscle during exercise, which might lead to cardiovascular complications such as chest pain and irregular heartbeat.
- Patients are advised to discontinue PRIMAL HYPER SHRED at least 2 weeks prior to any surgical procedures.
- Might affect blood glucose levels, which might interfere with blood glucose control in patients with diabetes mellitus (see section 4.5).
- Caution is advised for patients with existing renal or liver impairment.
- Patients with epilepsy should use PRIMAL HYPER SHRED with caution.
- Avoid taking with health products or foods that contain caffeine and/or increase blood pressure (e.g. medications, coffee, tea, colas, cocoa, guarana, mate, bitter orange extract, synephrine, octopamine, ephedra, ephedrine).
- Caffeine has been shown to reduce blood flow to the heart muscle during exercise which might lead to cardiovascular complications such as chest pain, and irregular heartbeat even in healthy individuals.
- If those symptoms occur, stop use and consult a health care provider.

#### Children and adolescents

The safety and efficacy of PRIMAL HYPER SHRED in children and adolescents has not yet been established. Consult a healthcare provider before use.

#### Other medicines and PRIMAL HYPER SHRED

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult a healthcare practitioner prior to use.

PRIMAL HYPER SHRED can interact with the following medications:

- Antidiabetic medicine:** Concomitant use of PRIMAL HYPER SHRED and antidiabetic medicine might interfere with blood glucose control and increase the risk of hypoglycaemia. Consult your doctor before using. Antidiabetic medicine includes glimepiride, insulin, metformin, and others.
- Antihypertensive medicine:** Consumption with other medicines which increase blood pressure (e.g. bitter orange extract, synephrine, octopamine, ephedra, ephedrine) is not recommended.
- Anticoagulant medicines:** PRIMAL HYPER SHRED may increase the risk of bleeding when used concomitantly with anticoagulant medicines (such as heparin or warfarin) or antiplatelet medicines (such as aspirin, clopidogrel, dipyridamole or ticlopidine).
- Anticonvulsant medicines** (such as carbamazepine, ethosuximide, felbamate, phenobarbital, phenytoin or valproate): as in PRIMAL HYPER SHRED may decrease the effects of anti-convulsant and increase the risk of seizures.
- Caffeine:** Consumption with other caffeine-containing products (e.g. medicines, coffee, tea, colas, cocoa, guarana, maté) is not recommended.
- Lithium:** Consult a health care provider prior to use if you are taking lithium.

#### Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using PRIMAL HYPER SHRED.

#### Driving and using machinery

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that PRIMAL HYPER SHRED does not adversely affect their performance.

#### 3. How to use PRIMAL HYPER SHRED

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use PRIMAL HYPER SHRED exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

**Adults 18 years and older:** Take 2 (two) capsules daily before your first meal, or as recommended by your healthcare provider. Use continuously for 4 weeks followed by a 2-week break.

#### Possible side effects

PRIMAL HYPER SHRED can have side effects. Not all side effects reported for PRIMAL HYPER SHRED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PRIMAL HYPER SHRED, please consult your doctor, pharmacist, or other healthcare practitioner for advice.

- Immune system disorders:** *Frequency unknown* - Hypersensitivity and/or allergic reactions.
- Endocrine disorders:** *Frequency unknown* - Hypoglycaemia, hypokalaemia, hyperninaemia.
- Gastrointestinal disorders:** *Frequency unknown* - Gastrointestinal irritation, abdominal pain, flatulence, constipation, nausea, vomiting, diarrhoea, decreased appetite.
- Skin and subcutaneous tissue disorders:** *Frequency unknown* - Skin rash, urticaria.
- Psychiatric disorders:** *Frequency unknown:* anxiety, agitation, irritability, mood changes.
- Nervous system disorders:** *Frequency unknown:* insomnia, nervousness, restlessness, tremors, convulsions, headache, sleep disturbances.
- Ear and labyrinth disorders:** *Frequency unknown:* ringing sound in the ears.
- Cardiac disorders:** *Frequency unknown:* tachycardia, chest pain, dysrhythmia.
- Respiratory, thoracic and mediastinal disorders:** *Frequency unknown:* quickened respiration, tachypnoea-induced respiratory alkalosis.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If any of the following happens, stop using PRIMAL HYPER SHRED and tell your doctor or pharmacist immediately, or go the casualty department of your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting. These are very serious side effects. If you have them, you may have had a serious reaction to PRIMAL HYPER SHRED. You may need urgent medical attention or hospitalisation.

#### Reporting of side effects

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PRIMAL HYPER SHRED.

#### 4. How to store PRIMAL HYPER SHRED

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused PRIMAL HYPER SHRED to your pharmacist.
- Do not dispose of unused PRIMAL HYPER SHRED in drains or sewerage systems (e.g. toilets).

#### 5. Contents of the pack and other information

What PRIMAL HYPER TEST contains

Each PRIMAL HYPER SHRED capsule contains:		% NRV*
Sinetrol® xpurC	315,00 mg	
[Citrus and guarana extracts, providing flavones from Naringin and Hesperidin (>40 %) and caffeine 3.3-4 %]		
<i>Ilex paraguariensis</i> (Yerba Mate)	250,00 mg	
[Leaf; 25,00 mg of a 10:1 extract]		
Total Caffeine	150,00 mg	
Caffeine anhydrous	137,40 mg	
Sinetrol® xpurC (3.3-4 %)	12,60 mg	
<i>Aframomum melegueta</i> (Grains of Paradise)	150,00 mg	
[xxxxx; 15,00 mg of a 10:1 extract]		
<i>Juniperus communis</i> (Juniper Berry)	12,50 mg	
[Fruit powder]		
L-Theanine	75,00 mg	
Chromium (as Chromium Polynicotinate)	50,00 µg	143 %
*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).		

Other ingredients: Microcrystalline cellulose and Magnesium stearate

Sugar free

#### Presentation and identification of PRIMAL HYPER TEST

60 White to off-white vegetable capsules, packed in a 300 ml black round PE container with a 60 mm PP round black screw cap with 56 mm induction seal (with air vent). A 65 mm x 10 mm round foam wad and a 0.5 g silica bag will be inserted.

#### Holder of Certificate of Registration

Manufactured for: The Dis-Chem Group, 23 Stag Road, Glen Austin, South Africa  
Careline: 0860 347 243; careline@dischem.co.za; www.dischem.co.za

#### This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

#### Registration number

Will be allocated by SAHPRA upon registration.  
Please see [www.dischem.co.za](http://www.dischem.co.za) for professional information.

## PASIËNTINLIGTINGSBLAD

### SKEDULERINGSSTATUS S0

Produknaam

## PRIMAL SPORTS NUTRITION HYPER SHRED

(Kapsules)

Elke PRIMAL HYPER SHRED kapsule bevat:		% NVW*
Sinetrol® xpurC	315,00 mg	
[Sitrus- en guarana-ekstrakte, verskaf flavone van Naringin en Hesperidin (>40 %) en kafeien 3.3-4 %]		
<i>Ilex paraguariensis</i> (Yerba Mate)	250,00 mg	
[blaar, 25,00 mg van 'n 10:1 ekstrak]		
Totale Kafeien	150,00 mg	
Anhidriese kafeien	137,40 mg	
Sinetrol® xpurC (3.3-4 %)	12,60 mg	
<i>Aframomum melegueta</i> (Grains of Paradise)	150,00 mg	
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<i>Juniperus communis</i> (Juniper Berry)	12,50 mg	
[Vrugte poeier]		
L-Teaniën	75,00 mg	
Chroom (as Chroompolynikotinaat)	50,00 µg	143 %
Suikervry		
*%Nutrientverwysingswaardes (NVWs) vir individue 4 jaar en ouer (2010).		

#### Komplementêre Medisyne: Gesondheidsaanvulling

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

#### Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.

PRIMAL HYPER SHRED is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet PRIMAL HYPER SHRED versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie PRIMAL HYPER SHRED met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u meer inligting of advies nodig het.

#### Wat is in hierdie inligtingsblad:

- Wat PRIMAL HYPER SHRED is en waarvoor dit gebruik word.
- Wat u moet weet voordat u PRIMAL HYPER SHRED gebruik.
- Hoe om PRIMAL HYPER SHRED te gebruik.
- Moontlike newe-effekte.
- Berging van PRIMAL HYPER SHRED.
- Inhoud van die verpakking en ander inligting

#### 1. Wat PRIMAL HYPER TEST is en waarvoor dit gebruik word

Aangedui as 'n hulpmiddel vir 'n gewigsbestuursprogram, in samewerking met 'n gebalanseerde dieet en oefenprogram.

#### 2. Wat u moet weet voordat u PRIMAL HYPER SHRED gebruik

##### Moet nie PRIMAL HYPER SHRED neem nie:

- Indien u 'n hipersensitiwiteit het vir enige van die bestanddele of die hulpstowwe gelys in 6.1.
- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy swanger is, of borsvoed.
- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy 'n nierversuuring het.
- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy ander diuretika gebruik.
- Nie aanbeveel vir gebruik by kinders onder die ouderdom van 18 jaar nie.

#### Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u PRIMAL HYPER SHRED gebruik, veral as u 'n mediese toestand het.

#### Gebruik PRIMAL HYPER TEST met omsigtigheid:

- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy swanger is, borsvoed of 'n nierversuuring het.
- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy ander diuretika gebruik.
- BEVAT KAFEÏEN. Nie geskik vir kinders onder die ouderdom van 18 jaar nie.
- Nie bedoel as 'n plaasvervanger vir slaap nie.
- Hipertensie, gloukoom en/of detrusor-onstabieliteit (ooraktiewe blaassindroom).
- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy hoë bloeddruk, gloukoom en/of detrusor-onstabieliteit (ooraktiewe blaassindroom) het. Die kafeïeninhoud kan hoë bloeddruk verhoog, intraokulêre druk verhoog en/of simptome van inkontinensie (soos urinêre frekwensie en dringendeheid) vererger.
- Kan bloeddioei na die hartspier verminder tydens oefening, wat kan lei tot kardiovaskulêre komplikasies soos borspyn en onreëlmatige hartklop.
- Pasiënte word aangeraai om PRIMAL HYPER SHRED ten minste 2 weke voor enige chirurgiese prosedures te staak.
- Kan bloedglukosevlakke beïnvloed, wat kan inneng met bloedglukosebeheer by pasiënte met diabetes mellitus (sien afdeling 4.5).
- Omsigtigheid word aangeraai vir pasiënte met bestaande nier- of lewersversaking.
- Pasiënte met epilepsie moet PRIMAL HYPER SHRED met omsigtigheid gebruik.
- Vermix innamie saam met gesondheidsprodukte of voedsel wat kafeïen bevat en/of bloeddruk verhoog (bv. medikasie, koffie, tee, cola, kakao, guarana, maat, bitterlemoene-ekstrak, sinefrien, oktopamien, efedra, efedrien).
- Daar is getoon dat kafeïen bloeddioei na die hartspier tydens oefening verminder, wat kan lei tot kardiovaskulêre komplikasies soos borspyn en onreëlmatige hartklop, selfs by gesonde individue.
- As daardie simptome voorkom, stop die gebruik en raadpleeg 'n gesondheidsorgverskaffer.

#### Kinders en adolessente

Die veiligheid en doeltreffendheid van PRIMAL APPELAsyn by kinders en adolessente is nog nie vasgestel nie. Raadpleeg 'n gesondheidsorgverskaffer voor gebruik.

#### Die neem van PRIMAL HYPER SHRED en ander medisyne

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

PRIMAL HYPER SHRED kan interaksie hê met die volgende medisyne:

- Antidiabetiese medisyne:** Gelyktydige gebruik van PRIMAL HYPER SHRED en antidiabetiese medisyne kan innemg met bloedglukosebeheer en die risiko van hipoglukemie verhoog. Raadpleeg jou dokter voor gebruik. Antidiabetiese medisyne sluit glimpeirid, insulien, metformin en ander in.
- Antihypertensiewe medisyne:** Verbruik saam met ander medisyne wat bloeddruk verhoog (bv. bitterlemoene-ekstrak, sinefrien, oktopamien, efedra, efedrien) word nie aanbeveel nie.
- Antistomiddelmedisyne:** PRIMAL HYPER SHRED kan die risiko van bloeding verhoog wanneer dit saam met antikoagulante medisyne (soos heparin of warfarin) of bloedplaatjie-medisyne (soos aspirien, klopidogrel, dipiridamol of tiklopidien) gebruik word.
- Antikonvulsiewe medisyne** (soos karbamasepine, etosuximied, felbamaat, fenobarbital, fenitoien of valproaat): soos in PRIMAL HYPER SHRED kan die effekte van anti-konvulsiewe middel verminder en die risiko van aanvalle verhoog.
- Kafeien:** Verbruik saam met ander kafeïenbevattende produkte (bv. medisyne, koffie, tee, cola, kakao, guarana, maté) word nie aanbeveel nie.
- Litium:** Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy litium neem.

#### Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u PRIMAL HYPER SHRED gebruik.

#### Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat PRIMAL HYPER SHRED nie hul werkverrigting nadelig beïnvloed nie.

#### 3. Hoe om PRIMAL HYPER SHRED te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik PRIMAL HYPER SHRED presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

**Volwassenes 18 jaar en ouer:** Neem 2 (twee) kapsules daaglik voor ete u eerste maaltyd, of soos aanbeveel deur jou gesondheidsorgverskaffer. Gebruik aaneenlopend vir 4 weke gevolg deur 'n 2 weke rus periode.

#### Moontlike newe-effekte

PRIMAL HYPER SHRED kan newe-effekte hê. Nie alle newe-effekte vir PRIMAL HYPER SHRED is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van PRIMAL HYPER SHRED, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

- Immuunstelselafwykings:** *Frekwensie onbekend* - Hipersensitiwiteit en/of allergiese reaksies.
- Endokriene versteurings:** *Frekwensie onbekend* - Hipoglukemie, hipokalemie, hiperreninemie.
- Gastroïntestinale versteurings:** *Frekwensie onbekend* - Gastroïntestinale irritasie, abdominale pyn, winderigheid, hardlywigheid, naarheid, braking, diarree, verminderde eetlus.
- Vel- en subkutane weefselafwykings:** *Frekwensie onbekend* - Veluitslag, urtikaria.
- Psigiatrisie versteurings:** *Frekwensie onbekend:* angs, agitatie, prikkelbaarheid, gemoedsveranderinge.
- Senuweestelselafwykings:** *Frekwensie onbekend:* slapeloosheid, senuweeagtigheid, rusteloosheid, bewing, stuiptrekkings, hoofpyn, slaapprobleme.
- Oor- en labirintafwykings:** *Frekwensie onbekend:* luikgeluid in die ore.
- Hartafwykings:** *Frekwensie onbekend:* tagikardie, borspyn, disritmie.
- Respiratoriese, torakale en mediastinale versteurings:** *Frekwensie onbekend:* versnelde respirasie, tagipnee-geïnduseerde respiratoriese alkalose.

Lig asseblief u dokter of apteker in indien u enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

As een van die volgende gebeur, hou op met die gebruik met PRIMAL HYPER SHRED en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongewasse afdeling van u naaste hospitaal: swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag, geïek, of floutes. Hierdie is baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op PRIMAL HYPER SHRED gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

#### Rapportering van newe-effekte

Praat met u dokter of apteker as u newe-effekte ervaar. U kan ook newe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van PRIMAL HYPER SHRED.

#### 4. Berging van PRIMAL HYPER SHRED

- Beskerm teen vog en berg by of onder 25 °C.
- HOU BUITE BEREÏK VAN KINDERS.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte PRIMAL HYPER TEST na u apteker terug.
- Moenie ongebruikte PRIMAL HYPER TEST in afvoertype of rioolsisteme (bv. toilette) weggooi nie.

#### 5. Inhoud van die verpakking en ander inligting

Wat PRIMAL HYPER SHRED bevat

Elke PRIMAL HYPER SHRED kapsule bevat:		% NVW*
Sinetrol® xpurC	315,00 mg	
[Sitrus- en guarana-ekstrakte, verskaf flavone van Naringin en Hesperidin (>40 %) en kafeien 3.3-4 %]		
<i>Ilex paraguariensis</i> (Yerba Mate)	250,00 mg	
[blaar, 25,00 mg van 'n 10:1 ekstrak]		
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[Vrugte poeier]		
L-Teaniën	75,00 mg	
Chroom (as Chroompolynikotinaat)	50,00 µg	143 %
*%Nutrientverwysingswaardes (NVWs) vir individue 4 jaar en ouer (2010).		

Ander bestanddele: Mikrokrystallose sellulose en magnesiumstearaat.

Suikervry

#### Aanbieding en identifikasie van PRIMAL HYPER SHRED

60 Wit tot spierwit groentekapsules, verpak in 'n 300 ml swart ronde PE-houer met 'n 60 mm PP ronde swart skroef dop met 56 mm induksie seël (met lugoppenging). 'n 65 mm x 10 mm ronde skuimprop en 'n 0,5 g silikasak sal ingesit word.

#### Houer van Registrasie-inligting

Vervaardig vir: The Dis-Chem Group, 23 Stag Road, Glen Austin, South Africa  
Sorglyn: 0860 347 243; careline@dischem.co.za; www.dischem.co.za

#### Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

#### Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.  
Raadpleeg [www.dischem.co.za](http://www.dischem.co.za) vir professionele inligting.

iO MEDIA	<b>PRODUCT:</b> Primal ; Hyper Shred ; 60's ; <b>STOCK:</b> Paper , <b>SPEC:</b> 250mm x 397mm	<b>6 June 2023</b>	Please confirm the following with a tick in each box: <input type="checkbox"/> BARCODE <input type="checkbox"/> SPELLING <input type="checkbox"/> LAYOUT <input type="checkbox"/> COLOURS
	<b>COLOUR (I):</b> <span style="display: inline-block; width: 15px; height: 15px; background-color: black; vertical-align: middle;"></span> K ;	<b>VI</b>	
	<b>FINISHING:</b>	<b>NOTES:</b> X	

## PROFESSIONAL INFORMATION

### D. 33.6 Western Herbal Substance. Complementary medicine: Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

## SCHEDULING STATUS S0

### 1. NAME OF THE MEDECINE

## PRIMAL SPORTS NUTRITION HYPER SHRED

(Capsules)

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each PRIMAL HYPER SHRED capsule contains:

Sinetrol® xpurC	315,00 mg	% NRV*
[Citrus and guarana extracts, providing flavones from Naringin and Hesperidin (>40 %) and caffeine 3.3-4 %]		
<i>Ilex paraguariensis</i> (Yerba Mate)	250,00 mg	
[Leaf; 25,00 mg of a 10:1 extract]		
Total Caffeine	150,00 mg	
Caffeine anhydrous	137,40 mg	
Sinetrol® xpurC (3.3-4 %)	12,60 mg	
<i>Aframomum melegueta</i> (Grains of Paradise)	150,00 mg	
[xxxxx; 15,00 mg of a 10:1 extract]		
<i>Juniperus communis</i> (Juniper Berry)	12,50 mg	
[Fruit powder]		
L-Theanine	75,00 mg	
Chromium (as Chromium Polynicotinate)	50,00 µg	143 %

\*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010). Sugar free

For full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Vegetable capsules.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Indicated as an aid to a weight management programme, in conjunction with a balanced diet and exercise program.

#### 4.2 Posology and method of administration

*Adults 18 years and older:* Take 2 (two) capsules daily before your first meal, or as recommended by your healthcare provider. Use continuously for 4 weeks followed by a 2-week break.

The safety and efficacy of PRIMAL HYPER SHRED in children and adolescents has not yet been established.

#### 4.3 Contraindications

- If you have a hypersensitivity to any of the ingredients or the excipients listed in 6.1.
- Consult a health care provider prior to use if you are pregnant or breastfeeding.
- Consult a healthcare provider prior to use if you have a kidney disorder.
- Consult a healthcare provider prior to use if you are taking other diuretics.
- Not recommended for use in children under the age of 18 years.

#### 4.4 Special warnings and precautions for use

Special care should be taken with PRIMAL HYPER SHRED

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Consult a healthcare provider prior to use if you are pregnant, breastfeeding or have a kidney disorder.
- Consult a healthcare provider prior to use if you are taking other diuretics.
- CONTAINS CAFFEINE. Not suitable for children under the age of 18 years.
- Not intended as a substitute for sleep.
- Hypertension, glaucoma and/or detrusor instability (overactive bladder syndrome).
- Consult a health care provider prior to use if you have high blood pressure, glaucoma, and/or detrusor instability (overactive bladder syndrome). The caffeine content may increase high blood pressure, increase intraocular pressure, and/or worsen symptoms of incontinence (such as urinary frequency and urgency).
- May reduce blood flow to the heart muscle during exercise, which might lead to cardiovascular complications such as chest pain and irregular heartbeat.
- Patients are advised to discontinue PRIMAL HYPER SHRED at least 2 weeks prior to any surgical procedures.
- Might affect blood glucose levels, which might interfere with blood glucose control in patients with diabetes mellitus (see section 4.5).
- Caution is advised for patients with existing renal or liver impairment.
- Patients with epilepsy should use PRIMAL HYPER SHRED with caution.
- Avoid taking with health products or foods that contain caffeine and/or increase blood pressure (e.g. medications, coffee, tea, colas, cocoa, guarana, mate, bitter orange extract, synephrine, octopamine, ephedra, ephedrine).
- Caffeine has been shown to reduce blood flow to the heart muscle during exercise which might lead to cardiovascular complications such as chest pain, and irregular heartbeat even in healthy individuals.
- If those symptoms occur, stop use and consult a health care provider.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

#### 4.5 Interaction with other medicines and other forms of interaction

##### Interactions with Medicines, Diseases / Impairments

- Antidiabetic medicine:** Concomitant use of PRIMAL HYPER SHRED and antidiabetic medicine might interfere with blood glucose control and increase the risk of hypoglycaemia. Consult your doctor before using. Antidiabetic medicine includes glibenclamide, insulin, metformin, and others.
- Antihypertensive medicine:** Consumption with other medicines which increase blood pressure (e.g. bitter orange extract, synephrine, octopamine, ephedra, ephedrine) is not recommended.
- Anticoagulant medicines:** PRIMAL HYPER SHRED may increase the risk of bleeding when used concomitantly with anticoagulant medicines (such as heparin or warfarin) or antiplatelet medicines (such as aspirin, clopidogrel, dipyridamole or ticlopidine).
- Anticonvulsant medicines** (such as carbamazepine, ethosuximide, felbamate, phenobarbital, phenytoin or valproate): as in PRIMAL HYPER SHRED may decrease the effects of anti-convulsant and increase the risk of seizures.
- Caffeine:** Consumption with other caffeine-containing products (e.g. medicines, coffee, tea, colas, cocoa, guarana, mate) is not recommended.
- Lithium:** Consult a health care provider prior to use if you are taking lithium.

##### Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting PRIMAL HYPER SHRED.

#### 4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established (see section 4.3).

#### 4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that PRIMAL HYPER SHRED does not adversely affect their performance.

#### 4.8 Undesirable effects

Orally, HYPER SHRED is well-tolerated.

#### Summary of adverse reactions

PRIMAL HYPER SHRED can have side effects.

- Immune system disorders:** *Frequency unknown* - Hypersensitivity and/or allergic reactions.
- Endocrine disorders:** *Frequency unknown* - Hypoglycaemia, hypokalaemia, hyperreninemia.
- Gastrointestinal disorders:** *Frequency unknown* - Gastrointestinal irritation, abdominal pain, flatulence, constipation, nausea, vomiting, diarrhoea, decreased appetite.
- Skin and subcutaneous tissue disorders:** *Frequency unknown* - Skin rash, urticaria.
- Psychiatric disorders:** *Frequency unknown:* anxiety, agitation, irritability, mood changes.
- Nervous system disorders:** *Frequency unknown:* insomnia, nervousness, restlessness, tremors, convulsions, headache, sleep disturbances.
- Ear and labyrinth disorders:** *Frequency unknown:* ringing sound in the ears.
- Cardiac disorders:** *Frequency unknown:* tachycardia, chest pain, dysrhythmia.
- Respiratory, thoracic and mediastinal disorders:** *Frequency unknown:* quickened respiration, tachypnoea-induced respiratory alkalosis.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If any of the following happens, stop using PRIMAL HYPER SHRED and tell your doctor or pharmacist immediately, or go the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting. These are very serious side effects. If you have them, you may have had a serious reaction to PRIMAL HYPER SHRED. You may need urgent medical attention or hospitalisation.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

#### 4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity. Treatment of overdose is symptomatic and supportive

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Mechanism of action:

- GUARANA:** Caffeine is often used in combination with ephedra for weight loss and seems to have additive pharmacodynamic effects.
- CITRUS BIOFLAVONOIDS:** the flavonoid constituents naringin and nobiletin, found in sweet orange, might have anti-inflammatory activity.
- YERBA MATE:** the effects of caffeine on energy expenditure and lipid metabolism seem to be mediated by both sympathetic and non-sympathetic mechanisms. Yerba mate may improve satiety, which might help reduce energy intake.
- CAFFEINE ANHYDROUS:** the thermogenic effects of caffeine may be due to vasoconstriction and increase in vascular smooth muscle tone.
- GRAINS OF PARADISE:** thought to have the potential to reduce body weight, improve body fat content, and increase energy expenditure through activation of the sympathetic nervous system, brown adipose tissue, and vanilloid receptor 1. These effects are purportedly due to the vanilloid moiety found on the structures of 6-paradol, 6-gingerol, and 6-shogaol, the major constituents found in grains of paradise seeds.
- JUNIPER BERRY:** the diuretic action of juniper has been attributed to terpinen-4-ol.
- L-THEANINE:** may act synergistically with caffeine and other constituents in green tea to cause weight loss.
- CHROMIUM:** Clinical research shows that ingestion of chromium picolinate reduces fat cravings, food intake, and hunger, which may lead to weight loss. Chromium may induce these effects by affecting the brain's hunger receptors.

### 5.2 Pharmacokinetic properties

**Guarana:** There is insufficient reliable information available about the pharmacokinetics of guarana.

**Citrus bioflavonoids:** There is insufficient reliable information available about the pharmacokinetics of citrus bioflavonoids.

#### Yerba mate

**Absorption:** After oral consumption of yerba mate, the gastrointestinal absorption of certain polyphenol constituents, such as di-hydrocaffeic, di-hydroferulic, and di-hydrocoumaric acids, can be delayed by colonic microbiota metabolism.

**Distribution:** High concentrations of caffeine and theobromine were found in the placenta, cord serum, neonatal urine, neonatal hair, meconium, and breast milk from a patient who reported drinking yerba mate during pregnancy.

#### Caffeine anhydrous

**Absorption:** Caffeine is rapidly and almost completely (99%) absorbed from the gut after ingestion. Peak levels in the circulation typically occur 30-60 minutes after ingestion.

**Distribution:** Caffeine is widely distributed throughout the tissues of the body after oral, rectal, or parenteral administration. It crosses the blood-brain barrier, so effects are exerted both centrally and peripherally.

**Metabolism:** Caffeine is metabolized in the liver by cytochrome P450 1A2 (CYP1A2) enzymes to paraxanthine (84%), theophylline (4%), and theobromine (12%).

**Excretion:** The half-life of caffeine in healthy adults is 1.5-10 hours and is decreased by smoking.

**Grains of Paradise,** there is insufficient reliable information available about the effectiveness of grains of paradise.

**Juniper Berry,** there is insufficient reliable information available about the pharmacokinetics of juniper.

#### L-theanine

**Absorption:** Theanine is absorbed through the intestines. The peak concentration of L-theanine in the plasma occurs at about 50 minutes after oral intake.

**Distribution:** Following absorption, L-theanine is distributed to the plasma and erythrocytes. L-theanine can cross the blood brain barrier and appears to do so in a dose-dependent manner.

**Metabolism:** L-theanine is hydrolyzed in the intestines to ethylamine and glutamic acid.

**Excretion:** A small amount of L-theanine is retained in erythrocytes, but most L-theanine and its metabolites are excreted in the urine 3-24 hours after oral intake.

#### Chromium:

When ingested, most chromium is excreted unabsorbed in the feces.

**Distribution:** After absorption, chromium is bound to transferrin. The distribution may occur across fast, medium, and slow compartments, with serum chromium not in equilibrium with tissue-organ stores.

**Excretion:** The small percentage of chromium that is absorbed is rapidly excreted in the urine.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Microcrystalline cellulose and Magnesium stearate.

### 6.2 Incompatibilities

No compatibility studies have been performed; PRIMAL HYPER SHRED must not be mixed with other medications.

### 6.3 Shelf Life

24 months

### 6.4 Special precautions for storage

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused PRIMAL HYPER SHRED to your pharmacist.
- Do not dispose of unused PRIMAL HYPER SHRED in drains or sewerage systems (e.g. toilets).

### 6.5 Nature and contents of container

60 White to off-white vegetable capsules, packed in a 300 ml black round PE container with a 60 mm PP round black screw cap with 56 mm induction seal (with air vent). A 65 mm x 10 mm round foam wad and a 0.5 g silica bag will be inserted.

### 6.6 Special precautions for disposal

No special requirements.

### 7. HOLDER OF CERTIFICATE OF REGISTRATION

Manufactured for: The Dis-Chem Group, 23 Stag Road, Glen Austin, South Africa  
Careline: 0860 347 243; careline@dischem.co.za; www.dischem.co.za

### 8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

### 9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

iOMEDIA	<b>PRODUCT:</b> Primal ; Hyper Shred ; 60's ; <b>STOCK:</b> Paper ; <b>SPEC:</b> 250mm x 397mm	<b>6 June 2023</b>	Please confirm the following with a tick in each box: <input type="checkbox"/> BARCODE <input type="checkbox"/> SPELLING <input type="checkbox"/> LAYOUT <input type="checkbox"/> COLOURS
	<b>COLOUR (I):</b> <span style="display: inline-block; width: 10px; height: 10px; background-color: black; vertical-align: middle;"></span> K ;	<b>VI</b>	
	<b>FINISHING:</b>	<b>NOTES:</b> X	