PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0 All pack sizes containing less than 25 tablets

S1 All pack sizes containing 25 or more tablets

DIS-CHEM PARACETAMOL 500 mg tablets

Paracetamol

Sugar free.

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

DIS-CHEM PARACETAMOL is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use DIS-CHEM PARACETAMOL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DIS-CHEM PARACETAMOL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days for pain in adults (5 days for children) and 3 days for fever.

What is in this leaflet:

1. What DIS-CHEM PARACETAMOL is and what it is used for
2. What you need to know before you take DIS-CHEM PARACETAMOL
3. How to take DIS-CHEM PARACETAMOL
4. Possible side effects
5. How to store DIS-CHEM PARACETAMOL
6. Contents of the pack and other information

1. What DIS-CHEM PARACETAMOL is and what it is used for

DIS-CHEM PARACETAMOL contains paracetamol, which is a painkiller which also reduces your temperature when you have a fever.

DIS-CHEM PARACETAMOL is used for the relief of mild to moderate pain and fever, such as headaches, toothache and pain associated with colds and flu, in adults and children older than 6 years of age.

2. What you need to know before you take DIS-CHEM PARACETAMOL

Do not take DIS-CHEM PARACETAMOL if you:

- Are hypersensitive (allergic) to paracetamol or any of the other ingredients of DIS-CHEM PARACETAMOL (listed in section 6 of this leaflet).
- Have severe liver problems.

Warnings and precautions:

Tell your doctor or health care provider before taking DIS-CHEM PARACETAMOL:

- If you have any liver or kidney problems.
- If you suffer from mild arthritis and need to take painkillers every day.
- If you have a severe infection, as DIS-CHEM PARACETAMOL can increase the risk of metabolic acidosis. Signs of metabolic acidosis include deep, rapid, difficult breathing; nausea or vomiting and loss of appetite.

Take special care with DIS-CHEM PARACETAMOL:

- If you take more tablets than the recommended quantity, it may cause liver damage.
- If you do not experience any relief with the recommended dosage, contact your doctor.
- If any new symptoms occur or if you experience redness or swelling, it may be a sign of a serious condition.

Children and adolescents:

Do not give DIS-CHEM PARACETAMOL to children under 6 years of age.

Where indicated in children do not give DIS-CHEM PARACETAMOL for more than 5 days for pain or more than 3 days for fever, without contacting your doctor.

Other medicines and DIS-CHEM PARACETAMOL:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not take DIS-CHEM PARACETAMOL with any other medicine that contains paracetamol.

Tell your doctor if you are taking:

- Metoclopramide or domperidone (for treating nausea and/or vomiting).
- Probenecid (to increase uric acid excretion in the urine).
- Colestyramine (to reduce blood fat levels).
- Aspirin (for treating pain, inflammation and fever).
- Warfarin and other anti-blood clotting medicine/anticoagulants (for prevention of blood clots).
- Isoniazid (an antibiotic medicine used to treat tuberculosis).

DIS-CHEM PARACETAMOL with food and drink:

There are no known interactions between DIS-CHEM PARACETAMOL, food and drink.

Pregnancy and breastfeeding:

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 health care provider for advice before taking DIS-CHEM PARACETAMOL.

Driving and using machines:

As it is unknown what side effects you may experience with the use of DIS-CHEM PARACETAMOL, caution is advised when driving or using machinery.

DIS-CHEM PARACETAMOL contains sodium metabisulphite:

DIS-CHEM PARACETAMOL contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm (difficulty breathing).

3. How to take DIS-CHEM PARACETAMOL

DO NOT TAKE MORE TABLETS THAN WHAT IS RECOMMENDED.

Do not share medicines prescribed for you with any other person. Always take DIS-CHEM PARACETAMOL exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

Children 6 – 12 years: Take half to one tablet every 6 hours, if it is necessary. Do not take more than 4 tablets per 24 hours.

Adults and children over 12 years: Take one to two tablets every four to six hours, if it is necessary. Do not take more than 8 tablets per 24 hours.

Swallow the tablet with water.

DIS-CHEM PARACETAMOL can be taken with or without food.

If you take more DIS-CHEM PARACETAMOL than you should:

In the event of overdosage, consult your doctor or pharmacist immediately even if you feel well. If neither is available, contact the nearest hospital or poison centre. Overdosage of DIS-CHEM PARACETAMOL can cause delayed, serious liver damage and treatment is required as soon as possible. Signs and symptoms of overdosage include yellowing of the skin or whites of the eyes, diarrhoea, increased sweating, loss of appetite, nausea or vomiting, stomach cramps or pain, swelling, pain or tenderness in the upper abdomen or stomach area.

4. Possible side effects

DIS-CHEM PARACETAMOL can have side effects.

Not all side effects reported for DIS-CHEM PARACETAMOL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DIS-CHEM PARACETAMOL, please consult your health care provider for advice.

If any of the following happens, stop taking DIS-CHEM PARACETAMOL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DIS-CHEM PARACETAMOL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Pinpoint red spots on your skin.
- Skin rash, hives or itching.
- Fever with or without chills (not present before you started taking DIS-CHEM PARACETAMOL or as a result of the condition being treated).
- Sores, ulcers, or white spots on your lips or in your mouth.
- Sore throat (not present before you started taking DIS-CHEM PARACETAMOL or as a result of the condition being treated).
- Unusual bleeding or bruising.
- Black, tarry stools.
- Blood in your stools or urine.
- Sudden decrease in amount of urine.
- Cloudy urine.
- Unusual tiredness or weakness.
- Severe and sharp pain in lower back and/or side.

- Breathing difficulties (coughing, tightness of chest, shortness of breath, wheezing). These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- Loss of liver function causing yellowed skin and eyes (jaundice) along with stomach pain and swelling.

These are all serious side effects. You may need urgent medical attention.

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DIS-CHEM PARACETAMOL.

5. How to store DIS-CHEM PARACETAMOL

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package/container.
- Protect from light.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/carton/bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DIS-CHEM PARACETAMOL contains:

The active substance is paracetamol. Each tablet contains 500 mg paracetamol.

The other ingredients are: gelatin, magnesium stearate, sodium metabisulphite, sodium starch glycolate, starch, talc, nipastat (preservative) and benzoic acid (preservative).

What DIS-CHEM PARACETAMOL looks like and the contents of the pack:

A flat, round, white, odourless tablet.

20 tablets: Blister strip of clear PVC film and aluminium foil containing 10 tablets each.

100 tablets: White, round securitainer with snap on cap, with desiccant and foam wadding.

Holder of certificate of registration:

Phyto OTC Health (Pty) Ltd

49 New Road

Midrand

1685

This leaflet was last revised:

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Registration number:

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30 July 1998

26806D03

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS

S0 Alle verpakkingsgroottes wat minder as 25 tablette bevat

S1 Alle verpakkingsgroottes wat 25 of meer tablette bevat

DIS-CHEM PARACETAMOL 500 mg tablette

Parasetamol

Suikervry.

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou:

DIS-CHEM PARACETAMOL is sonder ’n doktersvoorskrif beskikbaar, sodat jy ’n geringe ongesteldheid kan behandel. Jy moet DIS-CHEM PARACETAMOL nogtans sorgvuldig gebruik ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie DIS-CHEM PARACETAMOL met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of raad nodig het.
- Jy moet ’n dokter gaan spreek indien jou simptome vererger of die pyn nie binne 7 dae by volwassenes (5 dae vir kinders) verbeter nie, en koors binne 3 dae beter is nie.

Wat is in hierdie inligtingsblad:

1. Wat is DIS-CHEM PARACETAMOL en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy DIS-CHEM PARACETAMOL neem
3. Hoe om DIS-CHEM PARACETAMOL te neem
4. Moontlike newe-effekte
5. Hoe om DIS-CHEM PARACETAMOL te bêre
6. Inhoud van die pak en ander inligting

1. Wat is DIS-CHEM PARACETAMOL en waarvoor word dit gebruik

DIS-CHEM PARACETAMOL bevat parasetamol, wat ’n pynstiller is wat ook jou liggaamstemperatuur afbring wanneer jy koors het.

DIS-CHEM PARACETAMOL word gebruik vir die verligting van ligte tot matige pyn en koors, soos hoofpyn, tandpyn en pyn wat gepaardgaan met verkoue en griep, by volwassenes en kinders ouer as 6 jaar.

2. Wat jy moet weet voordat jy DIS-CHEM PARACETAMOL neem

Moenie DIS-CHEM PARACETAMOL neem nie indien jy:

- Hipersensitief (allergies) is vir parasetamol of vir enige van die ander bestanddele van DIS-CHEM PARACETAMOL (gelys by afdeling 6 van hierdie inligtingsblad).
- Erge lewerprobleme het.

Waarskuwings en voorsorgmaatreëls:

Voordat jy DIS-CHEM PARACETAMOL neem, sê vir jou dokter:

- Indien jy enige lewer- of nierprobleme het.
- Indien jy aan ligte artritis ly en elke dag pynstillers moet neem.
- Indien jy ’n hewige infeksie het, aangesien DIS-CHEM PARACETAMOL die risiko vir metaboliese asidose kan verhoog. Tekens van metaboliese asidose sluit in diep, vinnige, moeisame asemhaling; naarheid of braking en aptytverlies.

Wees versigtig met DIS-CHEM PARACETAMOL:

- Indien jy meer tablette as die aanbevole hoeveelheid neem, kan dit lewerskade veroorsaak.
- Indien jy nie enige verligting kry met die aanbevole dosis nie, kontak jou dokter.
- Indien enige nuwe simptome voorkom of jy rooiheid of swelling ervaar, mag dit tekens van ’n ernstige toestand wees.

Kinders en adolessente:

Moenie DIS-CHEM PARACETAMOL vir kinders jonger as 6 jaar gee nie.

Wanneer dit vir kinders aangedui word, moenie DIS-CHEM PARACETAMOL vir langer as 5 dae vir pyn of langer as 3 dae vir koors gee sonder om jou dokter te kontak nie.

Ander medisyne en DIS-CHEM PARACETAMOL:

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Moenie DIS-CHEM PARACETAMOL saam met enige ander medikasie wat parasetamol bevat neem nie.

Sê vir jou dokter indien jy die volgende gebruik:

- Metoklopramied of domperidoon (vir die behandeling van naarheid en/of braking).
- Probenesied (om die uitskeiding van uriensuur in die urine aan te help).
- Cholestiramien (om die hoeveelheid vette in die bloed te verlaag).
- Aspirien (vir die behandeling van pyn, inflammasie en koors).
- Warfarien en ander antistolmiddels/antikoagulante (vir die voorkoming van bloedklonte).
- Isoniasied (’n antibiotiese medisyne wat gebruik word om tuberkulose te behandel).

DIS-CHEM PARACETAMOL met kos en drinkgoed:

Daar is geen wisselwerking bekend tussen DIS-CHEM PARACETAMOL, kos en drinkgoed nie.

Swangerskap en borsvoeding:

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy DIS-CHEM PARACETAMOL neem.

Bestuur en die gebruik van masjiene:

Wees versigtig wanneer jy ’n voertuig bestuur of masjinerie gebruik, aangesien dit onbekend is watter newe-effekte jy mag ervaar wanneer jy DIS-CHEM PARACETAMOL gebruik.

DIS-CHEM PARACETAMOL bevat natriummetabisulfiet:

DIS-CHEM PARACETAMOL bevat natriummetabisulfiet, wat in seldsame gevalle hewige hipersensitiwiteitsreaksies en brongospasma (moeisame asemhaling) mag veroorsaak.

3. Hoe om DIS-CHEM PARACETAMOL te neem

MOENIE MEER TABLETTE NEEM AS WAT AANBEVEEL WORD NIE.

Moenie medisyne wat vir jou voorgeskryf is met enigiemand anders deel nie. Neem DIS-CHEM PARACETAMOL altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter, apteker of verpleegster vir jou gesê het. Vra gerus jou dokter, apteker of verpleegster indien jy onseker is.

Die gebruiklike dosis is:

Kinders 6 – 12 jaar: Neem ’n halwe tot een tablet elke 6 uur, indien nodig. Moenie meer as 4 tablette in 24 uur neem nie.

Volwassenes en kinders ouer as 12 jaar: Neem een tot twee tablette elke vier tot ses uur, indien nodig. Moenie meer as 8 tablette in 24 uur neem nie.

Sluk die tablet met water.

DIS-CHEM PARACETAMOL kan met of sonder kos geneem word.

Wat om te doen indien jy meer DIS-CHEM PARACETAMOL geneem het as wat jy moet:

In geval van oordosering, raadpleeg onmiddellik jou dokter of apteker, selfs al voel jy goed. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Oordosering met DIS-CHEM PARACETAMOL kan vertraagde, ernstige lewerskade veroorsaak en moet so gou as moontlik behandel word. Tekens en simptome van oordosering sluit in vergeling van die vel of die wit van die oë, diarree, verhoogde sweetafskeiding, aptytverlies, naarheid of braking, maagkrampe of pyn, swelling, pyn of gevoeligheid in die bobuik of die omgewing van die maag.

4. Moontlike newe-effekte

DIS-CHEM PARACETAMOL kan newe-effekte hê.

Nie alle newe-effekte wat vir DIS-CHEM PARACETAMOL gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl DIS-CHEM PARACETAMOL geneem word, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om DIS-CHEM PARACETAMOL te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe, mond, tong of keel, wat probleme kan veroorsaak met sluk of asemhaling.
- Uitslag of gejeuk.
- Floute.

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op DIS-CHEM PARACETAMOL gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:

- Speldpunt rooi kolletjies op jou vel.
- Veluitslag, galbulte of gejeuk.
- Koors met of sonder kouekoors (wat nie teenwoordig was voordat jy begin het om DIS-CHEM PARACETAMOL te neem nie, of wat voorkom as gevolg van die toestand wat behandel word nie).
- Sere, ulkusse, of wit kolle op jou lippe of in jou mond.
- Seer keel (wat nie teenwoordig was voordat jy begin het om DIS-CHEM PARACETAMOL te neem nie, of wat voorkom as gevolg van die toestand wat behandel word nie).
- Ongewone bloeding of kneusing.
- Swart, taai stoelgange.
- Bloed in jou stoelgang of urine.
- Skielik afname in die hoeveelheid urine.
- Troebel urine.
- Ongewone moegheid of swakheid.
- Hewige, skerp pyn in die lae rug en/of sy.
- Asemhalingsprobleme (hoes, benoude bors, kortasemheid, gehyg). Dit sal meer waarskynlik voorkom indien jy dit voorheen ervaar het toe jy ander pynstillers, soos ibuprofeen en aspirien, geneem het.

- Verlies van lewerfunksie, wat vergeling van die vel en oë veroorsaak (geelsug), met gepaardgaande maagpyn en swelling.

Hierdie is ernstige newe-effekte. Jy mag dringende mediese bystand benodig.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Rapportering van newe-effekte:

Bespreek dit met jou dokter of apteker indien jy newe-effekte ondervind. Jy kan ook newe-effekte by SAHPRA aanmeld deur die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: http://www.sahpra.org.za/Publications/Index/8. Deur newe-effek te rapporteer kan jy help om meer inligting rakende die veiligheid van DIS-CHEM PARACETAMOL te verskaf.

5. Hoe om DIS-CHEM PARACETAMOL te bêre

Bêre alle medisyne waar kinders dit nie in die hande kan kry nie.

- Bêre by of onder 25 °C.
- Bêre in die oorspronklike verpakking/houer.
- Beskerm teen lig.
- Moenie in die badkamer bêre nie.
- Moenie gebruik ná die vervaldatum wat op die etiket/karton/bottel voorkom nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) wegdoen nie.

6. Inhoud van die pak en ander inligting

Wat DIS-CHEM PARACETAMOL bevat:

Die aktiewe bestanddeel is parasetamol. Elke tablet bevat 500 mg parasetamol.

Die ander bestanddele is: gelatien, magnesiumstearaat, natriummetabisulfiet, natriumstyselglikolaat, stysel, talk, Nipastat (preserveermiddel) en bensoësuur (preserveermiddel).

Hoe DIS-CHEM PARACETAMOL lyk en inhoud van die verpakking:

'n Plat, ronde, wit, reuklose tablet.

20 tablette: Stulpstroke van deurskynende PVC-film en aluminiumfoelie, wat elk 10 tablette bevat.

100 tablette: Wit, ronde sekuriteitshouer met 'n aanknipdoppie, met 'n uitdroogmiddel en sponsie.

Houer van die registrasiesertifikaat:

Phyto OTC Health (Edms.) Bpk.

49 New Road

Midrand

1685

Hierdie inligtingsblad is laas hersien:

25 Maart 2021

Registrasienommer:

29/2.7/0287

Datum van registrasie:

30 Julie 1998

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