PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS

Solution for infusion

Paracetamol

Contains mannitol (36,7 mg/mL)

Read all of this leaflet carefully before you are given PARACETAMOL FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What PARACETAMOL FRESENIUS is and what it is used for
2. What you need to know before you are given PARACETAMOL FRESENIUS
3. How PARACETAMOL FRESENIUS will be administered to you
4. Possible side effects
5. How to store PARACETAMOL FRESENIUS
6. Contents of the pack and other information.

1. What PARACETAMOL FRESENIUS is and what it is used for

PARACETAMOL FRESENIUS belongs to a group of medicines called antipyretics or antipyretic and anti-inflammatory analgesics.

PARACETAMOL FRESENIUS is used in adults and children of at least 1 year old (and weighing at least 10 kg) for:

- the short-term treatment of mild to moderate pain such as dental procedures, minor surgery, and for
- the short-term treatment of fever when medicine cannot be swallowed.

2. What you need to know before you are given PARACETAMOL FRESENIUS

PARACETAMOL FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to paracetamol, pro-paracetamol hydrochloride, or any of the other ingredients in PARACETAMOL FRESENIUS (listed in section 6).
- if you have severe liver disease including alcoholic liver disease.
- children weighing less than 10 kg (approximately 1 year old).

Warnings and precautions

During treatment with PARACETAMOL FRESENIUS, tell your doctor straight away:

If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Take special care with PARACETAMOL FRESENIUS:

- if you are able to take medicine orally instead of an infusion
- if you are using any other medicines containing paracetamol

- if you have liver problems or any history of liver damage
- if you suffer from a inherited liver function disorder called Meulengracht Gilbert's syndrome
- if you have kidney problems or any history of kidney damage
- if you have glucose-6-phosphate dehydrogenase deficiency, an enzyme deficiency that may lead to red blood cell breakdown
- if you are using alcohol. Chronic use or excessive alcohol intake, i.e., three or more alcoholic drinks every day
- if you have an eating disorder such as anorexia or bulimia, or suspect that you may be undernourished or dehydrated
- talk to your doctor or pharmacist if you are taking or will be taking flucloxacillin. There is a risk of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when paracetamol is used concomitantly with flucloxacillin, particularly in certain groups of patients at risk, e.g., patients with severe renal impairment, sepsis or malnutrition, especially if the maximum daily doses of paracetamol are used. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.

Inform your doctor before treatment if any of the above mentioned conditions apply to you.

You should switch to taking pain killing tablets or syrup instead of PARACETAMOL FRESENIUS as soon as is possible.

Other medicines and PARACETAMOL FRESENIUS

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

Tell your doctor if you are taking any of the following:

- Amoxicillin, clavulanic acid (antibiotics used to treat infection).
- Anticoagulants (medicines used for blood thinning such as warfarin).
- Barbiturates (used for certain mental conditions), including primidone.
- Carbamazepine (used to treat epilepsy and certain nerve conditions).
- Flucloxacillin (an antibiotic used to treat infection), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- Isoniazid (used to treat tuberculosis).
- Metoclopramide (used for nausea and stomach problems).
- Phenytoin (medicine used for epilepsy), as it may cause damage to the liver.
- Probenecid (medicine for treatment of gout), as it may interfere with the clearing of paracetamol by the liver.
- Rifampicin (used to treat infections such as tuberculosis).
- Salicylamide (medicine for treatment of pain and fever), as it may interfere with the clearing of paracetamol by the liver.
- Zidovudine (an antiretroviral medicine used in HIV).

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 provider for advice before receiving PARACETAMOL FRESENIUS.

Driving and using machines

PARACETAMOL FRESENIUS has no influence on the ability to drive or use machines.

3. How PARACETAMOL FRESENIUS will be administered to you

You will not be expected to give yourself PARACETAMOL FRESENIUS. It will be given to you by a person who is qualified to do so.

PARACETAMOL FRESENIUS will be given to you by injection into a vein (intravenous infusion).

Adults:

The dose of PARACETAMOL FRESENIUS will be different for different patients.

Your doctor will decide on a suitable dose and the duration of the treatment based on your weight, your specific condition and needs.

Children:

Your child's doctor will work out what dose your child should receive, based on his/her weight. PARACETAMOL FRESENIUS is only given to children if they weigh more than 10 kg (approximately 1 year old). Tell your child's doctor if you have given any other paracetamol containing pain medicine to your child. The doctor needs this information to work out how much PARACETAMOL FRESENIUS your child can receive.

If you receive more PARACETAMOL FRESENIUS than you should

Since a healthcare provider will administer PARACETAMOL FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you receive higher doses than recommended, it can cause severe liver damage. The symptoms of liver damage are usually seen first after 2 days with the most severe symptoms experienced after 4 – 6 days. You may experience nausea, vomiting, anorexia (refusing to eat), pallor (pale skin) and abdominal pain and your doctor will treat these symptoms symptomatically. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage. You may also have liver damage which will be indicated by high blood levels of liver enzymes. Liver damage may lead to brain disease, coma and death.

Prompt treatment is essential. In the event of an overdosage or suspected overdose and notwithstanding the fact that you or your child may not have symptoms, consult a doctor, hospital or poison centre immediately. A delay in starting treatment may mean that the antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

If you forget to receive PARACETAMOL FRESENIUS

Since a healthcare provider will administer PARACETAMOL FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

PARACETAMOL FRESENIUS can have side effects.

Not all side effects reported for PARACETAMOL FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PARACETAMOL FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving PARACETAMOL FRESENIUS and tell your doctor immediately:

- Hypersensitivity and allergic reactions: any sudden wheeziness, difficulty in breathing, angioedema (swelling of the affected area with a burning sensation), swelling of the eyelids, face or lips and rash or itching (especially affecting your whole body), flushing (redness of the skin).

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Blood disorders characterised by unusual tiredness or weakness.
- Low blood pressure.
- Liver problems (you may notice signs like dark urine, pale-coloured stools, yellow skin and eyes, abdominal pain).
- Skin rash, itching, redness of skin and other skin conditions.
- Kidney problems (you may notice signs like cloudy urine, need to urinate frequently, burning urine and back pain).
- General feeling of unease, weakness or discomfort.
- Inflammation of the pancreas, stomach pain.
- Blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when paracetamol is used concomitantly with flucloxacillin, generally in the presence of risk factors (see section 2).

Side effects with an unknown frequency:

- A quick heartbeat.
- Nausea and vomiting.
- Pain and burning at the site of the injection.
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-

umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PARACETAMOL FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store PARACETAMOL FRESENIUS

Store all medicines out of reach of children.

Glass bottles: Store at or below 30 °C.

Free*flex*® bags: Store at or below 25 °C.

Do not refrigerate or freeze.

Once opened, the contents should be used immediately.

For single use only. Discard any unused portion.

Do not use after the expiry date stated on the label.

Do not use if you notice any particulate matter and discolouration.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Contents of the pack and other information

What PARACETAMOL FRESENIUS contains

The active substance is paracetamol.

Each 1 mL solution contains 10 mg paracetamol.

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS: Each 50 mL solution contains 0,5 g of paracetamol.

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS: Each 100 mL solution contains 1 g of paracetamol.

The other ingredients are cysteine, mannitol and water for injection.

Contains mannitol (36,7 mg/mL).

6. What PARACETAMOL FRESENIUS looks like and contents of the pack

Clear, colourless to slightly yellowish solution free from visible particulate contamination.

Packed into 50 mL or 100 mL clear, colourless glass bottles with a red rubber stopper and an aluminium cap, with either a tear-off tab of aluminium or a plastic lid or into 50 mL and 100 mL **Free*flex*®** bags (polyolefin) closed with stoppers and plastic tamper-evident covers.
10, 12 or 20 glass bottles of 50 mL or 100 mL are packed with a leaflet into a cardboard box.
10, 20, 50 or 60 **Free*flex*®** bags of 50 mL or 100 mL are packed with a leaflet into a cardboard box.

Not all pack sizes or container closure systems may be marketed.

Holder of Certificate of Registration

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Telephone number: +27 (0)11 545 0000

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Registration numbers

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS: 45/2.7/0531

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS: 45/2.7/1188

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS

Oplossing vir infusie

Parasetamol

Bevat mannitol (36,7 mg/mL)

Lees hierdie hele inligtingsblad aandagtig deur voordat PARACETAMOL FRESENIUS aan jou gegee word.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad

7. Wat is PARACETAMOL FRESENIUS en waarvoor word dit gebruik
8. Wat jy moet weet voordat jy PARACETAMOL FRESENIUS ontvang
9. Hoe PARACETAMOL FRESENIUS aan jou toegedien sal word
10. Moontlike newe-effekte
11. Hoe om PARACETAMOL FRESENIUS te bewaar
12. Inhoud van die pakkie en ander inligting.

1. Wat is PARACETAMOL FRESENIUS en waarvoor word dit gebruik

PARACETAMOL FRESENIUS behoort tot 'n groep medisyne genaamd antipiretika of antipiretika en anti-inflammatoriese analgetika.

PARACETAMOL FRESENIUS word gebruik by volwassenes en kinders van minstens 1 jaar oud (en wat minstens 10 kg weeg) vir:

- die korttermynbehandeling van ligte tot matige pyn soos tandheelkundige prosedures, geringe chirurgie, en vir
- die korttermynbehandeling van koors wanneer medisyne nie ingesluk kan word nie.

2. Wat jy moet weet voordat jy PARACETAMOL FRESENIUS ontvang

PARACETAMOL FRESENIUS moet nie aan jou toegedien word nie:

- indien jy hipersensitief (allergies) is vir parasetamol, pro-parasetamolhidrochloried, of enige van die ander bestanddele van PARACETAMOL FRESENIUS (gelys in afdeling 6).
- indien jy erge lewersiekte het, insluitende alkoholiese lewersiekte.
- kinders wat minder as 10 kg weeg (ongeveer 1 jaar oud).

Waarskuwings en voorsorgmaatreëls

Tydens behandeling met PARACETAMOL FRESENIUS, lig jou dokter dadelik in:

Indien jy ernstige siektes het, insluitend erge nierinkorting of sepsis (wanneer bakterieë en hul gifstowwe in die bloed sirkuleer en orgaanskade veroorsaak), of indien jy aan wanvoeding of chroniese alkoholisme ly, of as jy terselfdertyd flukloksasillien (’n antibiotikum) neem. 'n Ernstige toestand genaamd metaboliese asidose (’n bloed- en vloeistofafwyking) is in hierdie situasies by pasiënte aangemeld wanneer parasetamol vir 'n lang tydperk teen gereelde dosisse gebruik word of wanneer parasetamol saam met flukloksasillien geneem word. Simptome van metaboliese asidose kan ernstige asemhalingsprobleme met diep, vinnige asemhaling, lomerigheid, naarheid (mislike gevoel) en braking (opbring) insluit.

Wees versigtig met PARACETAMOL FRESENIUS:

- indien jy in staat is om medisyne per mond in te neem, in plaas van deur 'n infusie
- indien jy enige ander medisyne gebruik wat parasetamol bevat
- indien jy lewerprobleme of enige geskiedenis van lewerskade het
- indien jy aan 'n oorgeërfde lewerfunksieversteuring ly, genaamd Meulengracht Gilbert-sindroom
- indien jy nierprobleme of 'n geskiedenis van nierskade het
- indien jy 'n tekort aan glukose-6-fosfaat dehidrogenase het; dit is 'n ensiemtekort wat tot die afbraak van rooibloedselle kan lei
- indien jy alkohol gebruik. Chroniese of oormatige alkoholgebruik, dit wil sê drie of meer alkoholiese drankies elke dag
- indien jy 'n eetversteuring soos anoreksie of bulimie het, of as jy vermoed dat jy ondervoed of gedehidreer is
- praat met jou dokter of apteker indien jy flukloksasillien neem, of dit gaan neem. Daar is 'n risiko van bloed- en vloeistofafwykings (hoë-anioongaping metaboliese asidose), wat met verhoogde plasmasuurheid voorkom, wanneer parasetamol gelyktydig met flukloksasillien gebruik word, veral by sekere groepe pasiënte met 'n verhoogde risiko, byvoorbeeld, pasiënte met ernstige nierinkorting, sepsis of wanvoeding, veral as die maksimum daaglikse dosisse parasetamol gebruik word. Hoë-anioongaping metaboliese asidose is 'n ernstige siekte wat dringende behandeling benodig.

Lig jou dokter voor die behandeling in, indien enige van die bogenoemde toestande op jou van toepassing is.

Jy moet so gou as moontlik PARASETAMOL FRESENIUS vervang met pyntablette of -stroop.

Ander medisyne en PARACETAMOL FRESENIUS

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle

komplementêre of tradisionele medisyne in.)

Lig jou dokter in as jy enige van die volgende neem:

- Amoksisillien, klavulaansuur (antibiotika gebruik vir die behandeling van infeksie).
- Antistolmiddels (medisyne gebruik vir bloedverdunning, soos warfarien).
- Barbiturate (gebruik vir sekere geestestoestande), insluitend primidoon.
- Karbaamasepien (gebruik vir die behandeling van epilepsie en sekere senuweetoestande).
- Flukloksasillien (’n antibiotikum wat gebruik word om infeksie te behandel), as gevolg van ’n ernstige risiko van bloed- en vloeistofafwykings (genaamd metaboliese asidose) wat dringende behandeling benodig (sien afdeling 2).
- Isoniasied (gebruik vir die behandeling van tuberkulose).
- Metoklopramied (gebruik vir naarheid en maagprobleme).
- Fenitoïen (medisyne wat vir epilepsie gebruik word), want dit kan skade aan die lewer veroorsaak.
- Probenesied (medisyne vir die behandeling van jig), want dit kan die opklaring van parasetamol deur die lewer beïnvloed.
- Rifampisien (gebruik vir die behandeling van infeksies soos tuberkulose).
- Salisielamied (medisyne vir die behandeling van pyn en koors), want dit kan die opklaring van parasetamol deur die lewer beïnvloed.
- Sidovudien ('n antiretrovirale medisyne gebruik by MIV).

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy PARACETAMOL FRESENIUS ontvang.

Bestuur en die gebruik van masjinerie

PARACETAMOL FRESENIUS het geen invloed op die vermoë om te bestuur of masjinerie te gebruik nie.

3. Hoe PARACETAMOL FRESENIUS aan jou toegedien sal word

Daar sal nie van jou verwag word om PARACETAMOL FRESENIUS aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen.

PARACETAMOL FRESENIUS sal deur 'n inspuiting in 'n aar (intraveneuse infusie) aan jou toegedien word .

Volwassenes:

Die dosis PARASETAMOL FRESENIUS wissel van pasiënt tot pasiënt.

Jou dokter sal die toepaslike dosis en duur van die behandeling bepaal op grond van jou gewig, jou spesifieke gesondheidstoestand en jou behoeftes.

Kinders:

Jou kind se dokter sal die toepaslike dosis vir jou kind bereken op grond van sy/haar gewig. PARASETAMOL FRESENIUS word gewoonlik net aan kinders gegee as hulle meer as 10 kg weeg (ongeveer 1 jaar oud). Sê vir jou kind se dokter as jy enige ander pynstillers wat parasetamol bevat aan jou kind gegee het. Die dokter het hierdie inligting nodig om uit te werk hoeveel PARACETAMOL FRESENIUS jou kind kan ontvang.

Indien jy meer PARACETAMOL FRESENIUS ontvang het as wat jy moes

Aangesien 'n gesondheidsorgverskaffer PARACETAMOL FRESENIUS sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering behandel.

Indien jy hoër as die aanbevole dosisse ontvang, kan dit ernstige lewerskade veroorsaak. Die simptome van lewerskade word gewoonlik eers na 2 dae waargeneem en die ernstigste

simptome word na 4 - 6 dae ervaar. Jy kan naarheid, braking, anoreksie (weiering om te eet), bleekheid (bleek vel) en buikpyn ervaar en jou dokter sal hierdie simptome simptomaties behandel. Ligte simptome in die eerste twee dae na akute vergiftiging reflekteer nie die moontlike ernstigheid van die oordosering nie. Lewerskade kan ook teenwoordig wees, wat opgespoor kan word deur verhoogde bloedvlakke van lewerensieme. Lewerskade kan lei tot breinaandoening, koma en dood.

Onmiddellike behandeling is noodsaaklik. In die geval van 'n oordosis of vermoedelike oordosis, selfs al ervaar jy of jou kind dalk nie simptome nie, kontak dadelik 'n dokter, hospitaal of vergiftigingsentrum. ’n Vertraging in die aanvang van behandeling kan daartoe lei dat die teenmiddel te laat gegee word om doeltreffend te wees. Dikwels word lewerskade eers duidelik nadat die tyd vir effektiewe behandeling verby is.

Indien 'n dosis van PARACETAMOL FRESENIUS oorgeslaan word

Aangesien 'n gesondheidsorgverskaffer PARACETAMOL FRESENIUS sal toedien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

4. Moontlike newe-effekte

PARACETAMOL FRESENIUS kan newe-effekte hê.

Nie alle newe-effekte wat vir PARACETAMOL FRESENIUS aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy PARACETAMOL FRESENIUS ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om PARACETAMOL FRESENIUS te ontvang en lig jou dokter dadelik in:

- Hipersensitiwiteit en allergiese reaksies: skielike hyging, moeilike asemhaling, angio-edeem (swelling van die aangetaste area met 'n branderige gevoel), swelling van die

ooglede, gesig of lippe en uitslag of jeuk (veral oor die hele liggaam), blosing (rooiheid van die vel).

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, kan jy moontlik 'n ernstige reaksie op PARACETAMOL FRESENIUS hê. Jy kan dringende mediese aandag of verdere hospitalisasie benodig.

Lig jou dokter in as jy enige van die volgende waarneem:

Minder gereelde newe-effekte:

- Bloedafwykings gekenmerk deur ongewone moegheid of swakheid.
- Lae bloeddruk.
- Lewerprobleme (jy kan tekens opmerk soos donker urien, liggekleurde stoelgange, geel vel en oë, buikpyn).
- Veluitslag, jeuk, rooiheid van die vel en ander veltoestande.
- Nierprobleme (jy kan tekens soos troebel urien, drang om dikwels te urineer, branderige urien en rugpyn waarneem).
- Algemene gevoel van onrustigheid, swakheid of ongemaklikheid.
- Ontsteking van die pankreas, maagpyn.
- Bloed- en vloeistofafwykings (hoë-anioongaping metaboliese asidose) kom voor wanneer daar 'n toename in plasmasuurheid is, wanneer parasetamol gelyktydig met flukloksasillien gebruik word, gewoonlik in die teenwoordigheid van risikofaktore (sien afdeling 2).

Newe-effekte met 'n onbekende frekwensie:

- 'n Vinnige hartklop.
- Naarheid en braking.
- Pyn en branderigheid by die plek van inspuiting.
- By pasiënte met ernstige siekte wat parasetamol neem, kan 'n ernstige toestand voorkom waarby die bloed suurder word (metaboliese asidose) (sien afdeling 2).

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte

Indien jy newe-effekte ervaar, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) op die SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van PARACETAMOL FRESENIUS te verskaf.

Pasiënte word versoek om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan hulle gesondheidsorgverskaffer of die Houer van die Registrasiesertifikaat by die volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com en aan die betrokke medisyne se regulatoriese owerheid in die land waar die produk bemark word.

5. Hoe om PARACETAMOL FRESENIUS te bewaar

Bewaar alle medisyne buite bereik van kinders.

Glasbottels: Bewaar by of benede 30 °C.

Free*flex*® sakke: Bewaar by of benede 25 °C.

Moenie in 'n yskas of vrieskas plaas nie.

Sodra dit oopgemaak is, moet die inhoud dadelik gebruik word.

Slegs vir eenmalige gebruik. Gooi enige ongebruikte gedeelte weg.

Moenie na die vervaldatum wat op die etiket gedruk is, gebruik nie.

Moenie gebruik as jy enige deeltjies en verkleuring opmerk nie.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat PARACETAMOL FRESENIUS bevat

Die aktiewe bestanddeel is parasetamol.

Elke 1 mL oplossing bevat 10 mg parasetamol.

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS: Elke 50 mL oplossing bevat 0,5 g parasetamol.

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS: Elke 100 mL oplossing bevat 1 g parasetamol.

Die onaktiewe bestanddele is sisteïen, mannitol en water vir inspuiting.

Bevat mannitol (36,7 mg/mL).

Hoe PARACETAMOL FRESENIUS lyk en inhoud van die pakkie

'n Helder, kleurlose tot effens gelerige oplossing vry van sigbare kontaminasie met deeltjies.

Verpak in 50 mL of 100 mL helder, kleurlose glasbottels met 'n rooi rubberprop en 'n aluminiumdop, met óf 'n aluminium-aftrekoortjie óf 'n plastiekdeksel, of in 50 mL en 100 mL **Free*flex***®-sakke (poli-olefien) bedek met proppe en peutersigbare plastiekomhulsel.

10, 12 of 20 glasbottels van 50 mL of 100 mL word saam met 'n inligtingsblad in 'n kartondoos verpak.

10, 20, 50 of 60 **Free*flex*** ® sakke van 50 mL of 100 mL word met 'n inligtingsblad in 'n kartonhouer verpak.

Nie alle verpakkingsgroottes of houergroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat

Fresenius Kabi South Africa (Pty) Ltd

Erf 7, Growthpoint Business Park

Tonettistraat 162, Halfway House Extension 7

Midrand, Gauteng 1685

Suid-Afrika

Telefoonnommer: +27 (0)11 545 0000

Hierdie inligtingsblad is voorheen hersien in

21 Januarie 2026

Registrasienommers

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS: 45/2.7/0531

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS: 45/2.7/1188

Toegang tot die ooreenstemmende Professionele Inligting

Die professionele inligting sal gedruk word en saam met die produk verpak word.