**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS: S4**

**Busulfan 6 mg/ml Fresenius** Concentrate for solution for infusion

Busulfan

Sugar-free.

**Read all of this leaflet carefully before you are given Busulfan 6 mg/ml Fresenius**

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

**What is in this leaflet**


1. What **Busulfan 6 mg/ml Fresenius** is and what it is used for
2. What you need to know before you are given **Busulfan 6 mg/ml Fresenius**
3. How **Busulfan 6 mg/ml Fresenius** is given to you
4. Possible side effects
5. How to store **Busulfan 6 mg/ml Fresenius**
6. Contents of the pack and other information


## 1. What BUSULFAN 6 mg/ml FRESENIUS is and what it is used for

**Busulfan 6 mg/ml Fresenius** contains busulfan, which belongs to a group of medicines called alkylating agents.

**Busulfan 6 mg/ml Fresenius** destroys the original bone marrow before the transplant.

**Busulfan 6 mg/ml Fresenius** is used in adults as a treatment prior to transplantation in combination with cyclophosphamide.

You will receive this preparative medicine before receiving a transplant of either bone marrow or haematopoietic progenitor cell.

## 2. What you need to know before you are given Busulfan 6 mg/ml Fresenius

**Busulfan 6 mg/ml Fresenius should not be administered to you:**

- if you are hypersensitive (allergic) to Busulfan or any of the other ingredients of **Busulfan 6 mg/ml Fresenius** (listed in section 6).
- if you are pregnant, breastfeeding or think you may be pregnant .
- if you suffer from liver problems.

### Warnings and precautions

**Busulfan 6 mg/ml Fresenius** is a potent cytotoxic medicine that results in profound decrease of blood cells. At the recommended dose, this is the desired effect. Therefore, blood tests and careful monitoring will be performed throughout treatment and recovery period.

Your doctor may give you antibiotics to prevent and manage infection that may occur during your treatment.

Special care should be taken with **Busulfan 6 mg/ml Fresenius**

Tell your doctor or healthcare provider before being given the injection:

- if you have a liver, kidney, heart or lung problem.
- if you have a history of seizures, you should receive sufficient anti-epileptic or anti-seizure treatment.
- if you are currently taking other medicines.
- If you have previously had radiation therapy, chemotherapy or a progenitor cell transplant.

It is possible that use of **Busulfan 6 mg/ml Fresenius** may increase the risk of another malignancy in the future.

Formation of blood clots in the small blood vessels may appear after hematopoietic cell transplantation (HCT) with a high-dose of treatment in combination with other medicines.

**Other medicines and Busulfan 6 mg/ml Fresenius**

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

Particular caution should be taken if you use:

- itraconazole and metronidazole (used for certain types of infections) or ketobemidone (used to treat pain), because this may increase the side effects.
- Paracetamol (used to treat pain) during the 72 hours prior to or with **Busulfan 6 mg/ml Fresenius** administration should be used with caution.

**Interactions of Busulfan 6 mg/ml Fresenius with food, drink and alcohol**

None known.

**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 taking **Busulfan 6 mg/ml Fresenius**.

Women must not be pregnant during treatment with **Busulfan 6 mg/ml Fresenius** and up to 6 months after treatment.

Women must stop breastfeeding before starting their treatment with **Busulfan 6 mg/ml Fresenius.**

Adequate contraceptive precautions should be used when either partner is receiving **Busulfan 6 mg/ml Fresenius.**

As the product may cause infertility, it may no longer be possible for you become pregnant after treatment with busulfan.

The solvent dimethylacetanide (DMA) may also impair fertility.

If you are concerned about having children, you should discuss this with your doctor before treatment.

Men treated with **Busulfan 6 mg/ml Fresenius** are advised not to father a child during and up to 6 months after treatment and to seek advice on conservation of sperm prior to treatment because of the possibility of infertility due to therapy with **Busulfan 6 mg/ml Fresenius.**

**Driving and using machines**

It is not always possible to predict to what extent **Busulfan 6 mg/ml Fresenius** may

interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the extent to which **Busulfan 6 mg/ml Fresenius** affects them.

You may feel dizzy while taking this medicine. If this happens, do not drive or use any tools or machines until you are feeling well again.

**Busulfan 6 mg/ml Fresenius** contains macrogol 400 and the solvent, dimethylacetamide (DMA).

DMA may impair fertility.

**3. How Busulfan 6 mg/ml Fresenius is given to you**

Do not share medicines prescribed for you with any other person.

You will not be expected to inject yourself with **Busulfan 6 mg/ml Fresenius**. It will be given to you by a person who is qualified to do so.

In adults:

The usual dose of **Busulfan 6 mg/ml Fresenius** will be calculated according to your body weight.

The recommended dose of busulfan is 0,8 mg/kg.

Each infusion will last two hours.

**Busulfan 6 mg/ml Fresenius** will be administered every 6 hours during four consecutive days prior to the transplant.

**Before receiving Busulfan 6 mg/ml Fresenius you will be medicated with:**

- anticonvulsive medicines to prevent seizures (phenytoin or benzodiazepines) and
- antiemetic medicines to prevent vomiting.

**If you use more Busulfan 6 mg/ml Fresenius than you should**

Since a healthcare provider will administer **Busulfan 6 mg/ml Fresenius**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdose**.**

**If you forget to use Busulfan 6 mg/ml Fresenius**

Since a healthcare provider will administer **Busulfan 6 mg/ml Fresenius,** it is unlikely that the dose will be missed.

**4. Possible side effects**

**Busulfan 6 mg/ml Fresenius** can have side effects.

Not all side effects reported for **Busulfan 6 mg/ml Fresenius** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Busulfan 6 mg/ml Fresenius**, please consult your healthcare provider for advice.

If any of the following happens, tell your doctor or healthcare professional in the hospital immediately or if you are at home, go to the oncology clinic.

- an allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body), or feeling faint
- infection with symptoms of fever and chills, nausea and vomiting, body aches
- liver disorders including blocking of a liver vein (when the small blood vessels that lead into the liver and are inside the liver become blocked), enlarged liver, jaundice, graft versus host disease (the graft attacks your body)
- lung (pulmonary) complications - respiratory failure where usual exchange between

oxygen and carbon dioxide in the lungs does not occur, coughing up blood, collapse of small portions of the lung, fluid around the lung causing pain

- blood in the urine
- paralysis of the gut (muscle of the stomach is paralysed), vomiting blood, bleeding in the stomach and/or the gut
- cerebral haemorrhage (stroke), and seizure (fits)
- clotting of femoral artery

Your doctor will monitor your blood counts and liver enzymes regularly to detect and manage these events.

These are all very serious side effects. If you have them, you may have had a serious reaction to **Busulfan 6 mg/ml Fresenius**. 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:**

- decrease in urine output
- fluid retention or inflammation around the heart, decreased heart output
- depression
- increase in heart rate, increase or decrease of blood pressure, and blood clots
- inflammation of the mucosa (lining) of the mouth
- liquid in the abdomen
- chest pain, inflammation of the mucosa (lining)
- elevated liver enzymes
- changes and abnormalities in heart rhythm
- asthma

- inflammation of the mucosa of the oesophagus (lining of tube from the throat to stomach)
- moderate kidney insufficiency, kidney disorder
- damage to the brain that may result in abnormal brain function
- extra heart beats, decrease in heart rate, diffuse leak of fluid from the capillaries (small blood vessels)
- decrease in blood oxygen
- collection of pus that develops in the brain due to an infection known as brain abscess

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- insomnia, anxiety, dizziness
- loss of appetite, decrease in magnesium, calcium, potassium, phosphate, increase in blood enzyme albumin in blood, and increase in blood sugar
- shortness of breath, nasal secretion (rhinitis), sore throat, cough, hiccup, nosebleeds, abnormal breath sounds
- nausea, vomiting, abdominal pain, diarrhoea, constipation, heartburn, anal discomfort
- rash, itching, loss of hair
- back, muscle and joint pain
- increase in blood enzyme creatinine elimination, discomfort in urination
- fever, headache, weakness, chills, pain, oedema (swelling caused by buildup of liquid), general pain or inflammation at injection site

- increase in weight
- confusion, nervous system disorders
- low blood sodium
- increase in breath rhythm
- skin colour disorder, redness of the skin, skin desquamation (an unintended damage to and loss of the upper layer of skin)
- increase in the amount of nitrogen components in the blood stream

Less frequent side effects:

- an abrupt change in the brain that causes mental confusion and emotional disruption known as delirium, nervousness, hallucination, agitation

Frequency of side effects unknown:

- dysfunction of sexual glands
- lens disorders including clouding of the lens of the eye (cataract), and blurred vision (corneal thinning)
- menopausal symptoms and female infertility
- inflammation of the skin, generalised infection
- increase of the enzyme lactate dehydrogenase in the blood
- increase of waste by-product uric acid and urea in the blood
- incomplete development of teeth.

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

**Reporting of side effects**

If you suffer from side effects, talk to your doctor. 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 **Busulfan 6 mg/ml Fresenius.**

You should also report side effects to the Holder of Certificate of Registration, **Fresenius Kabi South Africa (Pty) Limited**

The contact details for our national reporting system are:

Email: safety.fksa@fresenius-kabi.com

Tel: +27 11 545 0000

Emergency: 0860 203 900

## 5. How to store Busulfan 6 mg/ml Fresenius

- Store all medicines out of reach of children.
- Hospital staff will store your medicine safely:
    - Store at or between 2 °C – 8 °C (in a refrigerator). Do not freeze.
    - Do not freeze the diluted solution.
    - Store in the original package/container.
    - Keep the container in the outer carton.
    - Keep the container tightly closed.
- Do not use after the expiry date stated on the label.
- 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 Busulfan 6 mg/ml Fresenius contains

- The active substance is busulfan.

  Each 1 ml concentrate contains 6 mg busulfan.

  Each vial contains 10 ml of concentrate.
- The other ingredients are dimethylacetamide and macrogol 400.

**What Busulfan 6 mg/ml Fresenius looks like and contents of the pack**

**Busulfan 6 mg/ml Fresenius** consists of a concentrate for solution for infusion and is supplied in 10 ml Type I, clear, colourless, tubular glass vials with a Teflon faced chlorobutyl grey rubber closure and sealed with an aluminium flip-off green overseal. Each vial may be shrink-wrapped along with a plastic bottom.

Pack sizes: 1 and 8 vials. Not all pack sizes may be marketed.

When diluted **Busulfan 6 mg/ml Fresenius** is a clear, colourless solution.

**Holder of Certificate of Registration**

**Fresenius Kabi South Africa (Pty) Ltd**

Stand 7, Growthpoint Business Park

162 Tonetti Street

Midrand, 1685

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**PASIËNTINLIGTINGSBLAD**

**SKEDULERINGSTATUS: S4**

**Busulfan 6 mg/ml Fresenius** konsentraat vir oplossing vir infusie

Busulfaan

Suikervry.

**Lees hierdie inligtingsblad aandagtig deur voordat Busulfan 6 mg/ml Fresenius aan jou toegedien word.**

- Hou hierdie inligtingsblad. Jy mag dit later weer wil lees
- Indien jy enige verdere vrae het, vra jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

**Wat is in hierdie inligtingsblad**


1. Wat is **Busulfan 6 mg/ml Fresenius** en waarvoor word dit gebruik
2. Wat jy moet weet voordat **Busulfan 6 mg/ml Fresenius** aan jou toegedien word
3. Hoe word **BUSULFAN 6 mg/ml Fresenius** aan jou toegedien
4. Moontlike newe-effekte
5. Hoe om **Busulfan 6 mg/ml Fresenius** te bewaar
6. Inhoud van die verpakking en ander inligting

## 1. wat is Busulfan 6 mg/ml Fresenius en waarvoor word dit gebruik

**Busulfan 6 mg/ml Fresenius** bevat busulfaan wat aan ‘n groep medisyne behoort wat alkilerende middels genoem word.

**Busulfan 6 mg/ml Fresenius** vernietig die oorspronklike beenmurg voor die oorplanting**.**

**Busulfan 6 mg/ml Fresenius** word gebruik by volwassenes as ‘n behandeling voor oorplanting in kombinasie met siklofosfamied.

Jy sal hierdie voorbereidende medisyne ontvang voor jy ‘n oorplanting van òf beenmurg òf hematopoiëtiese progenitor sel ontvang.

## 2. Wat jy moet weet voordat Busulfan 6 mg/ml Fresenius aan jou toegedien word.

**Busulfan 6 mg/ml Fresenius moet nie aan jou toegedien word nie:**

- indien jy hipersensitief (allergies) is vir busulfaan of enige van die ander bestanddele van **Busulfan 6 mg/ml Fresenius** (gelys in afdeling 6)
- indien jy swanger is, borsvoed of dink dat jy swanger mag wees
- indien jy aan lewerprobleme ly.

### Waarskuwings en voorsorgmaatreëls

**Busulfan 6 mg/ml Fresenius** is ‘n potente sitotoksiese medisyne wat tot aansienlike afname van bloedselle lei. Teen die aanbevole dosis, is dit die gewenste effek. Daarom, sal bloedtoetse en versigtige monitering deurgaans met behandeling en herstel uitgevoer word.

Jou dokter mag vir jou antibiotika voorskryf om infeksie wat tydens behandeling kan voorkom te verhoed en te hanteer.

Lig jou dokter of gesondheidsorgverskaffer in voordat die inspuiting aan jou gegee word:

Wees veral versigting vir **Busulfan 6 mg/ml Fresenius**

- indien jy ‘n lewer-, nier-, hart- of longprobleem het.
- indien jy ‘n geskiedenis het van aanvalle, behoort jy genoegsame anti-epileptiese of anti-stuip behandeling te ontvang.
- indien jy huidiglik ander medisyne neem.
- indien jy vantevore bestralingsterapie, chemoterapie of progenitor sel oorplanting gehad het.

Dit is moontlik dat gebruik van **Busulfan 6 mg/ml Fresenius** die risiko kan verhoog om in die toekoms aan ‘n ander kwaadaardigheid te ly.

Gevalle van vorming van bloedklonte in die klein bloedvate na hematopoiëtiese seloorplanting (HSO) Kan voorkom deur ‘n hoë dosis van behandeling in kombinasie met ander medisyne.

**Ander medisyne en Busulfan 6 mg/ml Fresenius**

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Bepaalde sorg moet geneem word indien jy die volgende gebruik:

- itrakonasool en metronidasool (gebruik vir sekere tipes van infeksies) of ketobemidoon (gebruik om pyn te behandel), want dit kan die newe-effekte verhoog.
- parasetamol (gebruik om pyn te behandel) gedurende die 72 uur voor of tydens **Busulfan 6 mg/ml Fresenius** toediening, moet met sorg gebruik word.

**Interaksies van Busulfan 6 mg/ml Fresenius met voedsel, vloeistowwe en alkohol**

Geen bekend.

**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 raad voordat jy **Busulfan 6 mg/ml Fresenius** ontvang.

Jy moenie swanger wees tydens behandeling met **Busulfan 6 mg/ml Fresenius** nie en moenie probeer om swanger te raak tot en met 6 maande na die behandeling nie.
Staak borsvoeding voordat jy met jou behandeling met **Busulfan 6 mg/ml Fresenius** begin**.**
Genoegsame voorbehoedvoorsorgmaatreëls moet gebruik word wanneer jy een of die ander vorm **Busulfan 6 mg/ml Fresenius** ontvang.
Dit mag moontlik wees dat jy nie meer swanger kan word nie (onvrugbaarheid) na die behandeling met **Busulfan 6 mg/ml Fresenius**.
Die oplosmiddel dimetielasetamied (DMA) kan ook vrugbaarheid beïnvloed.
Indien jy graag kinders wil hê, moet jy dit met jou dokter bespreek voor behandeling.
Mans wat met **Busulfan 6 mg/ml Fresenius** behandel word, word aangeraai om nie ‘n kind te verwek tydens en tot en met 6 maande na behandeling nie. Hulle moet raad inwin oor die bewaring van sperm voor behandeling omdat die behandeling met **Busulfan 6 mg/ml Fresenius** onvrugbaarheid tot gevolg mag hê.

**Bestuur en gebruik van masjinerie**

Dit is nie altyd moontlik om te voorspel to watter mate **Busulfan 6 mg/ml Fresenius** die daaglikse aktiwiteite van die pasiënt gaan beïnvloed nie. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is tot watter mate **Busulfan 6 mg/ml Fresenius** hulle aantas nie.

Jy kan duiselig voel terwyl jy hierdie medisyne neem. Indien dit gebeur moet jy nie bestuur of enige gereedskap of masjinerie gebruik nie, totdat jy weer goed voel.

**Busulfan 6 mg/ml Fresenius** bevat makrogol 400 en die oplosmiddel dimetielasetamied (DMA).

DMA mag vrugbaarheid benadeel.

**3. Hoe word Busulfan 6 mg/ml Fresenius aan jou toegedien**

Moet nie medisyne wat aan jou voorgeskryf is met enige ander persoon deel nie.

Daar sal nie van jou verwag word om **Busulfan 6 mg/ml Fresenius** aan jouself toe te dien nie. Dit sal aan jou toegedien word deur ‘n persoon wat gekwalifiseer is om dit te doen.

By volwassenes:

Die gebruiklike dosis van **Busulfan 6 mg/ml Fresenius** sal bereken word volgens jou liggaamsgewig.

Die aanbevole dosis van busulfaan is 0,8 mg/kg.

Elke infusie duur twee uur.

**Busulfan 6 mg/ml Fresenius** sal elke ses uur tydens vier opeenvolgende dae wat die oorplanting voorafgaan, toegedien word.

**Voordat jy Busulfan 6 mg/ml Fresenius ontvang sal jy medisinaal behandel word met:**

- antikonvulsiewe medisyne om aanvalle te verhoed (fenitoïen of bensodiasepiene) en
- anti-emetiese medisyne om braking te verhoed.

**Indien jy meer Busulfan 6 mg/ml Fresenius ontvang het as wat jy moet**

Aangesien jou gesondheidsorgverskaffer **Busulfan 6 mg/ml Fresenius** aan jou sal toedien, sal hy/sy die dosis beheer. Nietemin, in geval van ‘n oordosering, sal jou dokter die oordosis hanteer.

**Indien jy vergeet het om Busulfan 6 mg/ml Fresenius te gebruik**

Aangesien jou gesondheidsorgverskaffer **Busulfan 6 mg/ml Fresenius** sal toedien, is dit onwaarskynlik dat ‘n dosis oorgeslaan sal word.

**4. Moontlike newe-effekte**

**Busulfan 6 mg/ml Fresenius** kan newe-effekte hê.

Nie al die newe-effekte wat vir **Busulfan 6 mg/ml Fresenius** aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy **Busulfan 6 mg/ml Fresenius** gebruik, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, lig jou dokter of gesondheidsorgdeskundige by die hospitaal dadelik in, of indien jy tuis is gaan na jou onkologie kliniek.

- ‘n allergiese reaksie soos skielike hyging, moeilike asemhaling, swelling van die ooglede, gesig of lippe, uitslag of jeukerigheid (veral as die hele liggaam geaffekteer word) en jy voel asof jy gaan flou word

- infeksies met simptome van koors en koue rillings, naarheid en braking, liggaamspyne
- lewerafwykings insluitend blokkasie van ‘n leweraar (wanneer die klein bloedvate wat in die lewer ingaan en binne in die lewer is geblokkeer word), vergrote lewer, geelsug, transplantaat versus gasheer-siekte (die transplantaat val jou liggaam aan)
- long (pulmonêre) komplikasies – respiratoriese versaking waar gewoonlike uitruil tussen suurstof en koolstofdioksied in die longe nie voorkom nie, hoes van bloed, ineenstorting van klein gedeeltes van die long, vloeistof rondom die long wat pyn veroorsaak
- bloed in die uriene
- verlamming van die ingewande (maagspier is verlam), braking van bloed, bloeding in die maag en/of derms
- serebrale bloeding (beroerte), en aanvalle (stuipe)
- stolling van die femorale arterie

Jou dokter sal jou bloedtellings en lewerensieme gereeld moniteer om hierdie voorvalle op te spoor en te beheer.

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ervaar, kan jy moontlik ’n ernstige allergiese reaksie op **Busulfan 6 mg/ml Fresenius** gehad het. Jy kan dringende mediese aandag of hospitalisasie benodig.

**Lig jou dokter dadelik in of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy die volgende waarneem:**

- afname in urienlewering
- vloeistofretensie of inflammasie rondom die hart, afname in hartlewering
- depressie

- toename in harttempo, toename of afname in bloeddruk, en bloedklonte
- inflammasie van die mukosa (voering) van die mond
- vloeistof in die abdomen
- borspyn, inflammasie van die mukosa (voering)
- verhoogde lewerensieme
- veranderinge en abnormaliteite in hartritme
- asma
- inflammasie van die mukosa van die esofagus (voering van die buis van die keel na die maag)
- matige nierontoereikendheid, nierafwyking
- skade aan die brein wat tot ’n abnormale breinfunksie kan lei
- addisionele hartklop, afname in harttempo, verspreide lek van vloeistof vanuit die haarvate (klein bloedvate)
- afname in bloedsuurstof
- ophoping van etter wat in die brein ontwikkel as gevolg van ‘n infeksie bekend as breinabses

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

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

Dikwelse newe-effekte:

- slaaploosheid, angs, duiseligheid
- aptytsverlies, afname in magnesium, kalsium, kalium, fosfaat, toename in bloedensiem albumien in bloed, en toename in bloedsuiker
- kortasem, nasale afskeiding (rinitis), seer keel, hoes, hik, neusbloedings, abnormale asemgeluide

- naarheid, braking, abdominale pyn, diarree, konstipasie, sooibrand, anale ongemaklikheid
- uitslag, jeuk, haarverlies
- rug-, spier- en gewrigspyn,
- toename in bloedensiem kreatinien eliminasie, ongemak om te urineer
- koors, hoofpyn, swakheid, koue rillings, pyn, edeem (swelling veroorsaak deur die opbou van vloeistof), algemene pyn of inflammasie by die inspuitingsplek
- toename in gewig
- verwarring, senuweesisteemafwykings
- lae natrium in die bloed
- toename in asemritme
- velkleurafwyking, rooiheid van die vel, velafskilfering (‘n onopsetlike skade aan en verlies van die boonste laag van die vel)
- toename in die hoeveelheid stikstof komponente in die bloedstroom

Minder dikwelse newe-effekte:

- ‘n skielike verandering in die brein wat verstandelike verwarring en emosionele ontwrigting bekend as delirium, angstigheid, hallusinering, agitasie veroorsaak

Frekwensie van newe-effekte onbekend:

- sekslierdisfunksie
- lensafwykings insluitend vertroebeling van die lens of die oog (katarak), en dowwe visie (korneale verdunning)
- menopausale simptome en vroulike onvrugbaarheid
- inflammasie van die vel, algemene infeksie
- toename van die ensiem laktaatdehidrogenase in die bloed
- toename van die afval-byproduk uriensuur en ureum in die bloed

- onvolledige ontwikkeling van tande.

Indien jy enige newe-effekte waarneem wat nie in die voubiljet gelys is nie, lig jou dokter of apteker in.

**Aanmelding van newe-effekte**

Indien enige newe-effekte ondervind word, bespreek dit met jou dokter. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn onder SAHPRA se publikasies beskikbaar is: http://www.sahpra.org.za/Publications/Index/8.

Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van **Busulfan 6 mg/ml Fresenius** te verskaf.

Jy behoort ook newe-effekte by die Houer van Registrasiesertifikaat, **Fresenius Kabi South Africa (Pty) Limited** aan te meld**.**

Die kontakinligting vir ons nasionale aanmeldingsisteem is:

E-pos: safety.fksa@fresenius-kabi.com

Tel: +27 11 545 0000

Nood:  0860 203 900

**5. Hoe om Busulfan 6 mg/ml Fresenius te bewaar**

- Bewaar alle medisyne buite bereik van kinders.
- Hospitaalpersoneel sal die medisyne veilig bewaar:
    - Bewaar by of onder 2 °C – 8 °C (in 'n yskas). Moet nie vries nie.
    - Moenie die verdunde oplossing vries nie.
    - Bewaar in die oorspronklike verpakking/houer.

- Hou die houer in die buitenste karton.
- Hou die houer diggesluit.

- Moenie na die vervaldatum wat op die etiket gedruk is gebruik nie.
- Besorg alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

## 6. Inhoud van die verpakking en ander inligting

### Wat Busulfan 6 mg/ml Fresenius bevat

- Die aktiewe bestanddeel is busulfaan.

  Elke 1 ml konsentraat bevat 6 mg busulfaan.

  Elke flessie bevat 10 ml konsentraat.

- Die ander bestanddele is dimetielasetamied en makrogol 400.

### Hoe Busulfan 6 mg/ml Fresenius lyk en inhoud van die verpakking

**Busulfan 6 mg/ml Fresenius** bestaan uit ‘n konsentraat vir oplossing vir infusie en word voorsien in 10 ml Tipe I, helder, kleurlose, tubulêre glasflessies met ‘n Teflonaangesig chlorobutiel grys rubber-stopper en geseël met ‘n groen aluminium afknipdoppie.

Elke flessie mag krimpverpak wees saam met ‘n plastiekbodem.

Verpakkingsgroottes: 1 en 8 flessies. Nie al die verpakkingsgroottes word bemark nie.

Wanneer verdun is **Busulfan 6 mg/ml Fresenius** ‘n helder, kleurlose oplossing.

### Houer van die Registrasiesertifikaat

**Fresenius Kabi South Africa (Pty) Ltd**

Erf 7, Growthpoint Besigheidspark

162 Tonetti Straat,

Midrand, 1685

**Hierdie voubiljet was laas hersien in**

**Registrasienommer**

49/26/0087