PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

Leucovorin 50 mg/5 ml Fresenius

Leucovorin 100 mg/10 ml Fresenius

Leucovorin 200 mg/20 ml Fresenius

Leucovorin 350 mg/35 ml Fresenius

Leucovorin 500 mg/50 ml Fresenius

Leucovorin 1000 mg/100 ml Fresenius

Solution for injection or infusion

Folinic acid

Sugar free

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or other healthcare provider.
- LEUCOVORIN FRESENIUS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LEUCOVORIN FRESENIUS is and what it is used for
2. What you need to know before you use LEUCOVORIN FRESENIUS
3. How to use LEUCOVORIN FRESENIUS
4. Possible side effects

5. How to store LEUCOVORIN FRESENIUS
6. Contents of the pack and other information

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

LEUCOVORIN FRESENIUS contains folinic acid. The folinic acid is provided as calcium folinate (the calcium salt of folinic acid), which is related to the vitamin folic acid. Calcium folinate is a haematinic (it is a medicine that increases the haemoglobin content of the blood).

LEUCOVIRON FRESENIUS is used to:

- reduce the harmful effects and treat overdose of certain types of anti-cancer medicines, for instance methotrexate and other folic acid antagonists. This is known as “calcium folinate rescue” or “calcium leucovorin rescue”.
- LEUCOVORIN FRESENIUS increases the levels of folic acid in your body and may be used to improve the blood counts in certain anaemias (when you do not have enough red blood cells, due to folate deficiency).

2. What you need to know before you use LEUCOVORIN FRESENIUS

Do not use LEUCOVORIN FRESENIUS:

- if you are hypersensitive (allergic) to calcium folinate or any of the ingredients of LEUCOVORIN FRESENIUS (listed in section 6);
- if you suffer from pernicious anaemia or any type of anaemia where vitamin B12 is deficient.

Warnings and precautions

LEUCOVORIN FRESENIUS injection should only be given to you by intramuscular or intravenous injection/infusion and not by any other routes of administration. It must NOT be injected intrathecally (into the spine).

LEUCOVORIN FRESENIUS should only be used together with the cancer medicines methotrexate or 5-fluorouracil under the direct supervision of a doctor who has experience with the use of chemotherapeutic medicines in cancer.

Talk to your doctor before using LEUCOVORIN FRESENIUS:

- If you are taking any other cytotoxic medicines (hydroxycarbamide, cytarabine, mercaptopurine, thioguanine) as these can lead to macrocytosis (enlarged red blood cells).
- If you have epilepsy and are taking phenobarbital, phenytoin, primidone, and succinimides as there is a risk that your seizures (fits) may occur more often when you receive LEUCOVORIN FRESENIUS. Your doctor will decide if the dose of your anti-epileptic medicine has to be changed.
- If you have kidney problems, or develop kidney problems, your doctor might need to change your dose of LEUCOVORIN FRESENIUS if you are taking methotrexate (a medicine used in the treatment of cancer).
- If you suffer from a cancer of the central nervous system.

If you are to receive LEUCOVORIN FRESENIUS and 5-fluorouracil treatment at the same time, first tell your doctor if:

- you have had radiotherapy;
- you have stomach or bowel trouble.

  If you are elderly or feel unwell and you have to receive LEUCOVORIN FRESENIUS and 5-fluorouracil treatment at the same time, you may become more prone to infections and diarrhoea (see “Possible side effects”).

Other medicines and LEUCOVORIN FRESENIUS

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

Tell your doctor if you take:

- folic acid antagonists (for example, co-trimoxazole, pyrimethamine, methotrexate). The effectiveness of these medicines may either be reduced or neutralised;
- fluorouracil (anti-cancer medicine) – its efficacy and side effects will be increased by LEUCOVORIN FRESENIUS;
- medicines used to treat epilepsy (phenobarbital, phenytoin, primidone or succinimides) – the effectiveness of these medicines may be reduced by LEUCOVORIN FRESENIUS. Your doctor may check blood levels of these medicines and change your dose to prevent increased convulsions (fits);
- chloramphenicol (an antibiotic medicine).

This information may also apply to medicines that were used recently.

Fertility, 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 healthcare provider for advice before using LEUCOVORIN FRESENIUS.

Pregnancy:

Safety in pregnancy has not been established.

See patient information leaflets of other medicines that you may receive simultaneously for relevant information.

Breastfeeding:

Safety during breastfeeding has not been established. It is not known whether the active substance of LEUCOVORIN FRESENIUS (calcium folinate) is passed into human breastmilk.

See the patient information leaflets of all the other medicines that you may receive simultaneously for relevant information.

Fertility:

No information available.

Driving and using machines

If you suffer from fits and you are administered LEUCOVORIN FRESENIUS, you may have fits more frequently. Do not drive if this happens, as LEUCOVORIN FRESENIUS could interfere with your ability to drive safely. Do not operate any tools or machines.

LEUCOVORIN FRESENIUS contains sodium

LEUCOVORIN FRESENIUS contains 3,14 mg/ml to 3,20 mg/ml (0,14 mmol/ml) sodium. Tell your doctor if you need to stay on a low-salt diet.

3. How to use LEUCOVORIN FRESENIUS

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

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

LEUCOVORIN FRESENIUS solution may be given by injection (using a syringe) into a muscle, or it may be given by injection or infusion (drip) into a vein. If it is given by infusion LEUCOVORIN FRESENIUS injection will be diluted first.

Your doctor will work out the correct dose for you and how often and for how long it should be given. It will depend upon your medical condition, the dose of methotrexate you have been given and its elimination rate.

You will be closely monitored during the treatment.

The healthcare staff will prepare the LEUCOVORIN FRESENIUS injection.

If you use more LEUCOVORIN FRESENIUS than you should

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

If you forget to use LEUCOVORIN FRESENIUS

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

Please tell your doctor of pharmacist if you feel that the effect of LEUCOVORIN FRESENIUS is too strong or too weak.

4. Possible side effects

LEUCOVORIN FRESENIUS can have side effects.

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

See also patient information leaflets of anti-cancer and other medicines that you may be taking simultaneously.

If any of the following happens, stop receiving LEUCOVORIN FRESENIUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips and throat, rash or itching (especially affecting your whole body) these could be symptoms of an allergic reaction to this medicine.

These are all very serious side effects. If you have them, you may have had a serious reaction to LEUCOVORIN 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:

- fever after the injection
- severe diarrhoea and dehydration (loss of water). This is a very serious side effect which may be life-threatening and may prolong your hospital stay. Your doctor will decide if your treatment with 5-fluorouracil needs to be stopped until you feel better

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

Tell your doctor if you notice any of the following:

<u>Less frequent side effects:</u>

- an increase in convulsions (fits) in patients with epilepsy
- depression
- agitation (an inability to keep still)
- problems with the digestive system (vomiting, nausea, diarrhoea and loss of water (dehydration))
- trouble sleeping
- itchy rash
- thrombocytosis (a condition where your blood forms too many platelets). This will be detected with laboratory tests.

If you notice any side effects not listed 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 "**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 LEUCOVORIN FRESENIUS.

5. How to store Leucovorin Fresenius

Store all medicines out of reach of children.

The vials should be stored in a refrigerator (+2 °C to +8 °C). Keep the container in the carton to protect the contents from light.

For single use only. Discard any remaining solution.

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

Return all unused medicines to your pharmacist.

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

Shelf life after first opening or preparation

LEUCOVORIN FRESENIUS is intended for single use only.

After the container is first opened, any unused solution or remains of the solution for injection and infusion must be discarded.

Do not use this medicine if you notice clouding or particles are visible.

LEUCOVORIN FRESENIUS should be diluted immediately before use.

After dilution:

Chemical and physical in-use stability after dilution to 1,5 mg/ml with either 0,9 % sodium chloride solution or 5 % glucose solution was demonstrated for up to 28 days at both room temperature and 2-8 °C. From a microbial point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to

use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 ºC, unless reconstitution/ dilution has taken place in controlled and validated aseptic conditions.

6. Contents of the pack and other information

What LEUCOVORIN FRESENIUS contains

- The active substance is calcium folinate. Each ml contains 10 mg folinic acid provided as calcium folinate. Each 5, 10, 20, 35, 50, 100 ml vial contains 50, 100, 200, 350, 500 and 1 000 mg of folinic acid respectively (provided as calcium folinate).
- The other ingredients are sodium chloride, sodium hydroxide and water for injection.

What LEUCOVORIN FRESENIUS looks like and contents of the pack

LEUCOVORIN FRESENIUS is a clear, pale yellow to yellowish solution without visible particles, which is packed in vials.

The 5 ml, 10 ml, 20 ml, 35 ml, 50 ml or 100 ml vials are amber coloured, Ph. Eur Type I glass vial with grey chlorobutyl rubber stoppers and are respectively sealed with red, yellow, violet, white, brown and orange flip-off aluminium seals.

Pack sizes

1 vial, 5 vials and 10 vials for all sizes.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED

Stand No. 7, Growthpoint Business Park

162 Tonetti Street

Halfway House

South Africa

1685

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Registration Number

Leucovorin 50 mg/5 ml Fresenius: 50/8.3/0455

Leucovorin 100 mg/10 ml Fresenius: 50/8.3/0456

Leucovorin 200 mg/20 ml Fresenius: 50/8.3/0457

Leucovorin 350 mg/35 ml Fresenius: 50/8.3/0458

Leucovorin 500 mg/50 ml Fresenius: 50/8.3/0459

Leucovorin 1000 mg/100 ml Fresenius: 50/8.3/0460

Access to the corresponding Professional Information

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

PASIËNTINLIGTINGSBLAD

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Oplossing vir inspuiting of infusie

Foliniensuur

Suikervry

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

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy enige verdere vrae het, vra jou dokter, apteker of ander gesondheidsorgverskaffer.
- LEUCOVORIN FRESENIUS is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat is LEUCOVORIN FRESENIUS en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy LEUCOVORIN FRESENIUS gebruik
3. Hoe om LEUCOVORIN FRESENIUS te gebruik
4. Moontlike newe-effekte
5. Hoe om LEUCOVORIN FRESENIUS te bewaar

6. Inhoud van die verpakking en ander inligting

1. Wat is LEUCOVORIN FRESENIUS en waarvoor dit gebruik word

LEUCOVORIN FRESENIUS bevat foliniensuur. Die foliniensuur word verskaf as kalsiumfolinaat (die kalsiumsout van foliniensuur), wat verwant is aan die foliensuur vitamien. Kalsiumfolinaat is 'n hematinikum (dit is 'n medisyne wat die hemoglobieninhoud van die bloed verhoog).

LEUCOVORIN FRESENIUS word gebruik om:

- die skadelike effekte te verminder en oordosering te behandel van sekere tipes anti-kanker medisyne, byvoorbeeld metotreksaat en ander foliensuur-antagoniste. Dit staan bekend as "kalsiumfolinaat redding" of "kalsiumleukovirien redding".
- LEUCOVORIN FRESENIUS verhoog die vlakke van foliensuur in jou liggaam en kan gebruik word om die bloedtellings by sekere anemieë (wanneer jy weens folaat-tekort nie genoeg rooibloedselle het nie) te verbeter.

2. Wat jy moet weet voordat jy LEUCOVORIN FRESENIUS gebruik

Moenie LEUCOVORIN FRESENIUS gebruik nie:

- as jy hipersensitief (allergies) is vir kalsiumfolinaat of vir enige van die bestanddele van LEUCOVORIN FRESENIUS (gelys in afdeling 6);
- as jy ly aan pernisieuse anemie of enige tipe anemie waar daar 'n vitamien-B12 tekort is.

Waarskuwings en voorsorgmaatreëls

LEUCOVORIN FRESENIUS inspuiting moet slegs aan jou gegee word deur binnespierse of binneaarse inspuiting/infusie en nie deur enige ander toedieningsroetes nie. Dit moet NIE intratekaal (in die ruggraat) ingespuit word nie.

LEUCOVORIN FRESENIUS moet slegs saam met die kankermedisynes metotreksaat of 5-fluoorurasiel onder die direkte toesig van 'n dokter, wat ervare is met die gebruik van chemoterapeutiese medisynes in kanker, gebruik word.

Praat met jou dokter voordat LEUCOVORIN FRESENIUS gebruik word:

- As jy enige ander sitotoksiese medisynes neem (hidroksikarbamied, sitarabien, merkaptopurien, tioguanien) aangesien dit kan lei tot makrositose (vergrote rooibloedselle).
- As jy epilepsie het en fenobarbitaal, fenitoïen, primidoon, en suksienimiede neem, aangesien daar 'n risiko is dat jou aanvalle (stuipe) meer dikwels kan voorkom as jy LEUCOVORIN FRESENIUS ontvang. Jou dokter sal besluit of die dosis van jou anti-epileptiese medisyne verander moet word.
- As jy nierprobleme het, of nierprobleme ontwikkel, kan dit nodig wees dat jou dokter jou dosis van LEUCOVORIN FRESENIUS moet verander as jy metotreksaat ('n medisyne wat gebruik word met die behandeling van kanker) neem.
- As jy 'n tipe kanker van die sentrale senuweestelsel het.

As jy gelyktydig LEUCOVORIN FRESENIUS en 5-fluoorurasiel behandeling kry, sê eers vir jou dokter as:

- jy radioterapie gehad het;
- jy 'n maag- of dermprobleem het.

  As jy bejaard is of ongesteld voel en jy moet LEUCOVORIN FRESENIUS en 5-fluoorurasiel behandeling gelyktydig ontvang, kan jy meer geneig wees tot infeksies en diarree (kyk "Moontlike newe-effekte").

Ander medisynes en LEUCOVORIN 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 die volgende neem:

- foliensuur-antagoniste (soos byvoorbeeld ko-trimoksasool, pirimetamien, metotreksaat). Die doeltreffendheid van hierdie medisynes kan verminder of geneutraliseer word;
- fluoorurasiel (anti-kanker medisyne) - die doeltreffendheid en newe-effekte daarvan sal deur LEUCOVORIN FRESENIUS verhoog word;
- medisynes vir die behandeling van epilepsie (fenobarbitaal, fenitoïen, primidoon of suksienimiede) - die doeltreffendheid van hierdie medisynes kan verminder word deur LEUCOVORIN FRESENIUS. Jou dokter kan die bloedvlakke van hierdie medisyne kontroleer en jou dosis aanpas om verhoogde stuiptrekkings (stuipe) te voorkom;
- chlooramfenikol ('n antibiotiese medisyne).

Hierdie inligting kan ook van toepassing wees op medisynes wat onlangs gebruik is.

Vrugbaarheid, swangerskap en borsvoeding

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 voordat jy LEUCOVORIN FRESENIUS ontvang.

Swangerskap:

Veiligheid tydens swangerskap is nie bepaal nie.

Kyk pasiëntinligtingsblaaie van die ander medisynes wat jy gelyktydig ontvang vir toepaslike inligting.

Borsvoeding:

Veiligheid tydens borsvoeding is nie bepaal nie. Dit is nie bekend of die aktiewe bestanddeel van LEUCOVORIN FRESENIUS (kalsiumfolinaat) in mens borsmelk uitgeskei word nie.

Kyk pasiëntinligtingsblaaie van al die ander medisynes wat jy gelyktydig ontvang vir toepaslike inligting.

Vrugbaarheid:

Geen inligting beskikbaar.

Bestuur en gebruik van masjinerie

As jy las het van stuipe en LEUCOVORIN FRESENIUS word toegedien, kan jy dalk meer gereeld aanvalle kry. Moenie bestuur as dit gebeur nie, want LEUCOVORIN FRESENIUS kan jou vermoë om veilig te bestuur belemmer. Moenie enige gereedskap of masjinerie hanteer nie.

LEUCOVORIN FRESENIUS bevat natrium

LEUCOVORIN FRESENIUS bevat 3,14 mg/ml tot 3,20 mg/ml (0,14 mmol/ml) natrium. Sê vir jou dokter as jy op 'n sout-beperkende dieet is.

3. Hoe om LEUCOVORIN FRESENIUS te gebruik

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

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

LEUCOVORIN FRESENIUS oplossing kan met 'n inspuiting (met behulp van 'n spuit) in 'n spier toegedien word, of dit kan deur inspuiting of infusie (indruppeling) in 'n aar toegedien word. As dit deur infusie gegee word sal LEUCOVORIN FRESENIUS inspuiting eers verdun word.

Jou dokter sal die regte dosis vir jou uitwerk en hoe gereeld en hoe lank dit gegee moet word. Dit sal afhang van jou mediese toestand, die dosis metotreksaat wat jy ontvang het en die uitskeidingstempo.

Jy sal noukeurig gemoniteer word tydens die behandeling.

Die mediese personeel sal die inspuiting met LEUCOVORIN FRESENIUS berei.

As jy meer LEUCOVORIN FRESENIUS gebruik het as wat jy moes

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

Indien jy vergeet om LEUCOVORIN FRESENIUS te gebruik

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

Lig jou dokter of apteker in as jy dink dat die effek van LEUCOVORIN FRESENIUS te sterk of te swak is.

4. Moontlike newe-effekte

LEUCOVORIN FRESENIUS kan newe-effekte hê.

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

Kyk ook pasiëntinligtingsblaaie van die antikankermiddels en ander medisynes wat jy gelyktydig ontvang.

Indien enige van die volgende gebeur, hou op om LEUCOVORIN FRESENIUS te ontvang en lig jou dokter dadelik in, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- skielike hyging, asemhalingsprobleme, swelling van die ooglede, gesig of lippe en keel, uitslag of jeuk (veral oor jou hele liggaam); dit kan simptome wees van 'n allergiese reaksie op hierdie medisyne.

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ervaar, kan jy moontlik 'n ernstige reaksie op LEUCOVORIN FRESENIUS hê. Jy kan dringende mediese aandag of hospitalisering benodig.

Lig jou dokter dadelik in as jy enige van die volgende tekens waarneem, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- koors na die inspuiting
- erge diarree en dehidrasie (vogverlies). Dit is 'n baie ernstige newe-effek wat lewensgevaarlik kan wees en jou hospitaalverblyf kan verleng. Jou dokter sal besluit of jou behandeling met 5-fluoorurasiel moet stop totdat jy beter voel

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

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

<u>Minder gereelde newe-effekte:</u>

- 'n toename in konvulsies (stuipe) by pasiënte met epilepsie
- depressie
- agitasie ('n onvermoë om nie te beweeg nie)
- probleme met die spysverteringstelsel (braking, naarheid, diarree en waterverlies (dehidrasie))
- slaapprobleme
- jeukerige uitslag
- trombositose ('n siektetoestand waarby jou bloed te veel bloedplaatjies vorm). Dit sal met laboratoriumtoetse opgespoor word.

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 enige newe-effekte ondervind word, bespreek dit met jou dokter, apteker of verpleegster. 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 LEUCOVORIN FRESENIUS te verskaf.

5. Hoe om LEUCOVORIN FRESENIUS te bewaar

Bewaar alle medisyne buite bereik van kinders.

Die flessies moet in 'n yskas (+2 °C tot +8 °C) bewaar word. Hou die flessies in die karton om dit teen lig te beskerm.

Slegs vir eenmalige gebruik. Gooi enige oorblywende oplossing weg.

Moenie gebruik ná die vervaldatum wat op die karton of etiket gedruk is nie.

Neem alle ongebruikte medisynes terug na jou apteker.

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

Rakleeftyd nadat dit oopgemaak is of voorberei is

LEUCOVORIN FRESENIUS is slegs vir eenmalige gebruik.

Nadat die houer vir die eerste keer oopgemaak is, moet alle ongebruikte oplossing of oorblyfsels van die oplossing vir inspuiting en infusie weggegooi word.

Moenie hierdie medisyne gebruik as jy sien dat dit troebel is of as jy sigbare deeltjies waarneem nie.

LEUCOVORIN FRESENIUS moet onmiddellik voor gebruik verdun word.

Na verdunning:

Chemiese en fisiese stabiliteit tydens gebruik na verdunning tot 1,5 mg/ml met óf 0,9 % natriumchloriedoplossing óf 5 % glukose-oplossing is aangetoon vir maksimum 28 dae

by sowel kamertemperatuur as 2-8 °C. Vanuit 'n mikrobiese oogpunt moet die produk onmiddellik gebruik word. Indien dit nie dadelik gebruik word nie, is die in-gebruik bergingstye en toestande voor gebruik die verantwoordelikheid van die gebruiker en sou dit normaalweg nie langer as 24 uur by 2-8 °C wees nie, tensy hersamestelling/ verdunning onder gekontroleerde en gevalideerde toestande plaasgevind het.

6. Inhoud van die verpakking en ander inligting

Wat LEUCOVORIN FRESENIUS bevat

- Die aktiewe bestanddeel is kalsiumfolinaat. Elke ml bevat 10 mg foliniensuur wat as kalsiumfolinaat verskaf word. Elke 5, 10, 20, 35, 50, 100 ml flessie bevat onderskeidelik 50, 100, 200, 350, 500 en 1 000 mg foliniensuur (voorsien as kalsiumfolinaat).
- Die ander bestanddele is: natriumchloried, natriumhidroksied en water vir inspuiting.

Hoe LEUCOVORIN FRESENIUS lyk en wat die inhoud van die verpakking is

LEUCOVORIN FRESENIUS is 'n deursigtige, liggeel tot gelerige oplossing sonder sigbare deeltjies, wat in flessies verpak is.

Die 5 ml, 10 ml, 20 ml, 35 ml, 50 ml of 100 ml flessies is amberkleurig, Ph. Eur. Tipe I-flessie met grys chloorbutielrubber proppe en is onderskeidelik met rooi, geel, pers, wit, bruin en oranje afwip-aluminiumbedekkings verseël.

Verpakkingsgroottes

1 flessie, 5 flessies en 10 flessies vir al die groottes.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat

FRESENIUS KABI SOUTH AFRICA (PTY) LIMITED

Erf 7, Growthpoint Business Park

Tonettistraat 162

Halfway House

Suid-Afrika

1685

Hierdie inligtingsblad is laas hersien in

Registrasienommer

Leucovorin 50 mg/5 ml Fresenius: 50/8.3/0455

Leucovorin 100 mg/10 ml Fresenius: 50/8.3/0456

Leucovorin 200 mg/20 ml Fresenius: 50/8.3/0457

Leucovorin 350 mg/35 ml Fresenius: 50/8.3/0458

Leucovorin 500 mg/50 ml Fresenius: 50/8.3/0459

Leucovorin 1000 mg/100 ml Fresenius: 50/8.3/0460

Toegang tot die ooreenstemmende Professionele Inligting

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