PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

DOXORUBICIN 2 mg/ml (10 mg/5 ml) FRESENIUS concentrate for solution for infusion

DOXORUBICIN 2 mg/ml (50 mg/25 ml) FRESENIUS concentrate for solution for infusion

Doxorubicin hydrochloride

Sugar free

Read all of this leaflet carefully before you are given DOXORUBICIN 2 mg/ml 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 DOXORUBICIN 2 mg/ml FRESENIUS is and what it is used for
2. What you need to know before you use DOXORUBICIN 2 mg/ml FRESENIUS
3. How to use DOXORUBICIN 2 mg/ml FRESENIUS
4. Possible side effects
5. How to store DOXORUBICIN 2 mg/ml FRESENIUS
6. Contents of the pack and other information

1. What DOXORUBICIN 2 mg/ml FRESENIUS is and what it is used for

Doxorubicin is one of a group of medicines known as anthracyclines. Doxorubicin works by killing tumour and blood cancer cells.

DOXORUBICIN 2 mg/ml FRESENIUS is used in the treatment of various cancers to slow or stop the growth of cancer cells. A combination of different types of cancer medicines will often be used to achieve better results and minimise side effects.

Your doctor will be able to explain how DOXORUBICIN 2 mg/ml FRESENIUS might help in your particular condition.

2. What you need to know before you use DOXORUBICIN 2 mg/ml FRESENIUS

Do not use DOXORUBICIN 2 mg/ml FRESENIUS

- if you are hypersensitive (allergic) to doxorubicin hydrochloride, or any of the other ingredients of DOXORUBICIN 2 mg/ml FRESENIUS (listed in section 6)
- if you are allergic to any other anthracycline
- if you have been told your blood is thin (your bone marrow is not working well)
- if your liver is not working well
- if you suffer from heart disease
- if you had a recent heart attack
- serious abnormality of the heartbeat (dysrhythmia)
- if you have previously been treated with doxorubicin or similar chemotherapy medicines like, idarubicin, epirubicin or daunorubicin, as previous treatment with these similar medicines can increase the risk of side effects with DOXORUBICIN 2 mg/ml FRESENIUS
- if you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

DOXORUBICIN 2 mg/ml FRESENIUS will only be used in specialised departments of oncology (cancer) and will be administered under the supervision of doctor experienced in cancer chemotherapy.

Tell your doctor or health care provider before being given the injection:

- if you suffer from liver disease
- if you suffer from mouth ulcers
- if you have secondary acute myelogenous leukaemia (AML), a type of cancer of the blood cells

Site of administration:

Avoid any contact with your skin and mucous membranes.

Tell your doctor as soon as you experience stinging or redness at the site of injection. The infusion will immediately be stopped and restarted in another vein.

Skin reactions due to previous cancer therapy may recur with administration of DOXORUBICIN 2 mg/ml FRESENIUS.

DOXORUBICIN 2 mg/ml FRESENIUS irritates the skin and thrombophlebitis (inflammation of the vein with formation of a clot) and streaking of the skin over the vein used for infusion may occur and it should not be confused with extravasation (stinging or burning at injection site).

Cardiac risk with administration of DOXORUBICIN 2 mg/ml FRESENIUS:

Your doctor will monitor your heart function carefully during the treatment because:

DOXORUBICIN 2 mg/ml FRESENIUS may damage the heart muscle and may lead to heart failure after a certain cumulative dose (adding up of single doses). The risk for

heart muscle damage is higher if you have previously received medicines that may damage the heart or radiotherapy of the upper body.

If you are on this treatment you will undergo frequent ECG monitoring and if your doctor finds any abnormalities, he/she will discontinue treatment or do further evaluation tests.

Myelosuppression with the administration of DOXORUBICIN 2 mg/ml FRESENIUS:

You may suffer from myelosuppression (a reduction in bone marrow activity that leads to a lower concentration of platelets, red blood cells and white blood cells). This may make you more prone to infections or bleeding.

Your doctor will conduct blood tests regularly to monitor your blood cells.

Other safety information

DOXORUBICIN 2 mg/ml FRESENIUS may enhance the toxicity of other anticancer therapies. Your doctor will ensure that the necessary tests are done to monitor these effects.

The levels of uric acid (showing that cancer cells are destroyed) in your blood may be high during treatment. Your doctor will tell you if you need to take any medicine to control this.

Existing infections should be treated before DOXORUBICIN 2 mg/ml FRESENIUS therapy is started.

DOXORUBICIN 2 mg/ml FRESENIUS is generally not recommended in combination with live, attenuated vaccines. Contact to persons recently vaccinated against polio should be avoided.

You may experience changes in your menstrual cycle and your ability to conceive may be affected.

DOXORUBICIN 2 mg/ml FRESENIUS may give a red colour to your urine, which should not be mistaken for blood. This is a normal effect of the medicine that does not pose any health hazards.

Other medicines and DOXORUBICIN 2 mg/ml FRESENIUS

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

The following medicines may interact with DOXORUBICIN 2 mg/ml FRESENIUS:

- other cancer medicines e.g. trastuzumab, anthracyclines (daunorubicin, epirubicin, idarubicin), cisplatin, cyclophosphamide, ciclosporin, cytarabine, dacarbazine, dactinomycin, fluorouracil, mitomycin C, taxanes (e.g. paclitaxel), mercaptopurine, methotrexate, streptozocin, 6- mercaptopurine
- medicines for heart disease e.g. calcium channel blockers, verapamil, and digoxin
- ciclosporin (an immune suppressant medicine)
- ritonavir (a medicine used for HIV treatment)
- clozapine (an antipsychotic medicine used in schizophrenia)
- amphotericin B (medicines used against fungal diseases)
- uric acid lowering medicines (one example is allopurinol), as their dose may need adjustment
- radiotherapy: any radiotherapy treatment before, during and after DOXORUBICIN 2 mg/ml FRESENIUS may increase the toxic effects on the heart and liver
- live vaccines (e.g. polio (myelitis), malaria)
- phenytoin (a medicine used to prevent and control seizures).

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 DOXORUBICIN 2 mg/ml FRESENIUS.

Pregnancy

Your doctor will not administer DOXORUBICIN 2 mg/ml FRESENIUS if you are pregnant (see “Do not use DOXORUBICIN 2 mg/ml FRESENIUS”).

Breastfeeding

Do not breastfeed while you are treated with DOXORUBICIN 2 mg/ml FRESENIUS. The medicine can be passed on to the baby through the breast milk.

Fertility

If you are a woman, you should not get pregnant during treatment with DOXORUBICIN 2 mg/ml FRESENIUS or up to 6 months after treatment.

If you are a man, you should take adequate precautions to ensure that your partner does not become pregnant during your treatment with DOXORUBICIN 2 mg/ml FRESENIUS or up to 6 months after treatment and to seek advice on cryo-conservation (or cryo-preservation) of sperm prior to treatment because of the possibility of irreversible infertility due to therapy with DOXORUBICIN 2 mg/ml FRESENIUS. If you are considering becoming parents after the treatment, please discuss this with your doctor.

Driving and using machines

Nausea and vomiting frequently occur. If you experience these adverse effects, you should avoid driving and operating machinery while on therapy with DOXORUBICIN 2 mg/ml FRESENIUS.

DOXORUBICIN 2 mg/ml FRESENIUS contains sodium

DOXORUBICIN 2 mg/ml FRESENIUS contains 0,15 mmol (3,5 mg) sodium per ml. This should be considered if you are on a controlled sodium diet.

3. How to use DOXORUBICIN 2 mg/ml FRESENIUS

You will not be expected to give yourself DOXORUBICIN 2 mg/ml FRESENIUS. It will be given to you by a person who is qualified to do so.

DOXORUBICIN 2 mg/ml FRESENIUS can only be given under supervision by a doctor with experience in cancer treatment.

Your doctor will calculate your dosage according to your body surface area, your condition and the cancer to be treated.

DOXORUBICIN 2 mg/ml FRESENIUS will be administered intravenously (injected into a vein). The dose will be repeated at intervals determined by your doctor. Your doctor will tell you how long your treatment with DOXORUBICIN 2 mg/ml FRESENIUS will last.

If you have the impression that the effect of DOXORUBICIN 2 mg/ml FRESENIUS is too strong or too weak, tell your doctor.

If you receive more DOXORUBICIN 2 mg/ml FRESENIUS than you should:

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

The symptoms of overdosage will be an extension of the side effects. Please tell your doctor if you experience a worsening of any of the side effects.

If you forget to use DOXORUBICIN 2 mg/ml FRESENIUS

Since a healthcare provider will administer DOXORUBICIN 2 mg/ml FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

DOXORUBICIN 2 mg/ml FRESENIUS can have side effects.

Not all side effects reported for DOXORUBICIN 2 mg/ml FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DOXORUBICIN 2 mg/ml FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop using DOXORUBICIN 2 mg/ml FRESENIUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, face, lips or throat, which may cause difficulty breathing,
- rash or itching, hives, red swollen skin.

These are all serious side effects. If you have them you may have a serious reaction to DOXORUBICIN 2 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:

- fever (high temperature), chills, shivering and fast heartbeat (sepsis, blood poisoning)
- anaemia (a low red blood cell count) that can leave you feeling tired and lethargic
- low blood platelet count that could make you bleed or bruise more easily
- low white blood cell counts (these cells fight infection), increasing the chance of infections and raised temperature (fever)
- decreased activity in your bone marrow, affecting your immunity against infections. Your doctor should test your blood cell count during treatment
- abnormal increase or irregularity in heart rate (cardiomyopathy, dysrhythmias)
- shortness of breath, swollen legs (congestive heart failure)
- intestinal perforation (blood in the stool, severe abdominal pain, nausea and vomiting blood)
- acute renal failure (decreased urine output, swelling of legs, fatigue)
- pain and swelling at the injection site.

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:

- anorexia
- nausea
- vomiting
- swollen or sore mouth
- diarrhoea
- loss of hair
- facial flushing

Less frequent side effects

- dehydration (loss of water, feeling thirsty)
- headache
- eye infection
- excessive secretion of tears
- low blood pressure
- inflammation in vein (phlebitis)
- inflammation of the food pipe (painful swallowing)
- abdominal pain
- ulcers in the intestines and mouth
- excessive pigmentation of skin and nails
- detached nails
- urine might appear red in colour

- gout (high uric acid)
- absence of menstruation
- reduced sperm volume
- enlarged breasts
- feeling unwell
- weakness
- shivering
- dizziness

Frequency unknown:

- thromboembolism (clot formed in a blood vessel)
- excessive pigmentation of oral mucosa - feeling of intense heat (hot flushes)
- inflammation of the large intestine (colitis)
- liver disorders (yellowing of skin and eyes, increase in liver enzyme blood test results)
- tissue hypoxia (low oxygen in your tissues) (your skin may feel cold and if severe take on a bluish colour)
- plantar-palmar dysaesthesia (hand-to-foot syndrome is a distinctive and relatively frequent skin toxic reaction)
- photosensitivity
- no sperm formation
- asthenia (loss or lack of bodily strength; weakness; debility)
- thrombophlebitis (vein inflammation under the skin)

- a stinging or burning sensation at the administration site in relation to extravasation. Extravasation can lead to local death of calls of the tissue which may require surgical measures.

If you notice any of 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 "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 DOXORUBICIN FRESENIUS 2 mg/ml.

5. How to store DOXORUBICIN 2 mg/ml FRESENIUS

Store all medicines out of reach of children.

Store at 2 °C - 8 °C. Do not freeze. Keep vial in carton to protect from light. Store in upright position.

Infusion preparation:

DOXORUBICIN 2 mg/ml FRESENIUS is for single use only. Any unused solution should be discarded.

After dilution with 0,9 % sodium chloride or dextrose 5 % in water the diluted solution should be used immediately. Any unused solution should be discarded.

6. Contents of the pack and other information

What DOXORUBICIN 2 mg/ml FRESENIUS contains

- The active substance is doxorubicin hydrochloride. Each ml of the concentrate for solution for infusion contains 2 mg doxorubicin hydrochloride.

Each 5 ml vial contains 10 mg doxorubicin hydrochloride.

Each 25 ml vial contains 50 mg doxorubicin hydrochloride.

- The inactive ingredients are sodium chloride and water for injection.

What DOXORUBICIN 2 mg/ml FRESENIUS looks like and contents of the pack

DOXORUBICIN 2 mg/ml FRESENIUS is a clear red solution, filled in clear glass vial when examined under suitable conditions of visibility it should be free from particles.

DOXORUBICIN 10 mg/5 ml FRESENIUS is packed in 5 ml clear colourless type I moulded glass vial with 5 ml fill, plugged with bromobutyl grey rubber stoppers with aluminium flip off seal.

Each vial may be shrink wrapped along with a plastic bottom and packaged in a mono-carton.

Not all pack sizes may be marketed.

DOXORUBICIN 50 mg/25 ml FRESENIUS is packed in 30 ml clear colourless type I, moulded glass vial with 25 ml fill, plugged with bromobutyl grey rubber stoppers with aluminium flip off seal.

Each vial may be shrink wrapped along with a plastic bottom and packaged in a mono-carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Fresenius Kabi South Africa (Pty) Limited

Stand 7 Growthpoint Business Park

162 Tonetti Street

Midrand, South Africa

This leaflet was last revised in

Registration numbers

Doxorubicin 10 mg/5 ml Fresenius: 48/26/0937

Doxorubicin 50 mg/25 ml Fresenius: 48/26/0938

Access to the corresponding Professional Information

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

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: **S4**

DOXORUBICIN 2 mg/ml (10 mg/5 ml) FRESENIUS konsentraat vir oplossing vir infusie

DOXORUBICIN 2 mg/ml (50 mg/25 ml) FRESENIUS konsentraat vir oplossing vir infusie

Doksorubisienhidrochloried

Suikervry

Lees hierdie hele inligtingsblad aandagtig deur voordat DOXORUBICIN 2 mg/ml FRESENIUS aan jou gegee word

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

Wat is in hierdie pamflet

1. Wat DOXORUBICIN 2 mg/ml FRESENIUS is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy DOXORUBICIN 2 mg/ml FRESENIUS gebruik
3. Hoe om DOXORUBICIN 2 mg/ml FRESENIUS te gebruik
4. Moontlike newe-effekte
5. Hoe om DOXORUBICIN 2 mg/ml FRESENIUS te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat DOXORUBICIN 2 mg/ml FRESENIUS is en waarvoor dit gebruik word

Doksorubisien is een van 'n groep medisynes wat bekend staan as antrasikliene. Doksorubisien werk deur tumor- en bloedkankerselle dood te maak.

DOXORUBICIN 2 mg/ml FRESENIUS word gebruik by die behandeling van verskillende vorme van kanker om die groei van kankerselle te vertraag of te stop. 'n Kombinasie van verskillende soorte kankermedisynes word dikwels gebruik om beter resultate te bereik en newe-effekte te beperk.

Jou dokter sal vir jou kan verduidelik hoe DOXORUBICIN 2 mg/ml FRESENIUS kan help by jou spesifieke toestand.

2. Wat jy moet weet voordat jy DOXORUBICIN 2 mg/ml FRESENIUS gebruik

Moenie DOXORUBICIN 2 mg/ml FRESENIUS gebruik nie

- Indien jy hipersensitief (allergies) is vir doksorubisienhidrochloried of vir enige van die ander bestanddele van DOXORUBICIN 2 mg/ml FRESENIUS (gelys in afdeling 6)
- as jy allergies is vir enige ander antrasiklien
- as daar vir jou gesê is dat jou bloed te dun is (jou beenmurg nie goed werk nie)
- as jou lewer nie goed werk nie
- as jy aan hartsiekte ly
- as jy onlangs 'n hartaanval gehad het
- ernstige abnormaliteit van die hartklop (disritmie)

- as jy voorheen behandel is met doksorubisien of soortgelyke medisynes vir chemoterapie soos idarubisien, epirubisien of dounorubisien, aangesien vorige behandeling met hierdie soortgelyke medisyne die risiko vir newe-effekte met DOXORUBICIN 2 mg/ml FRESENIUS kan verhoog
- as jy swanger is of borsvoed (kyk Swangerskap en borsvoeding).

Waarskuwings en voorsorgmaatreëls

DOXORUBICIN 2 mg/ml FRESENIUS word slegs in gespesialiseerde afdelings van onkologie (kanker) gebruik en sal toegedien word onder toesig van 'n dokter wat ervaring het met chemoterapie by kanker.

Sê vir jou dokter of gesondheidsorgverskaffer voordat die inspuiting aan jou gegee word:

- as jy ly aan lewersiekte
- as jy ly aan mondsere
- as jy sekondêre akute miëlogene leukemie (AML) het, 'n soort kanker van die bloedselle

Plek van toediening:

Vermy kontak met jou vel en slymvliese.

Sê vir jou dokter sodra jy prikkeling of rooiheid op die inspuitplek ervaar. Die infusie sal dadelik gestaak word en in 'n ander aar voortgesit word.

Velreaksies veroorsaak deur vorige kankerbehandeling kan weer voorkom met die toediening van DOXORUBICIN 2 mg/ml FRESENIUS.

DOXORUBICIN 2 mg/ml FRESENIUS irriteer die vel en tromboflebitis (ontsteking van die aar met die vorming van 'n bloedklont) en strepe van die vel oor die aar wat vir

infusie gebruik word, kan voorkom en dit moet nie verwar word met ekstravasasie (prikkelrigheid of branderige gevoel op die inspuitplek nie).

Kardiale risiko by toediening van DOXORUBICIN 2 mg/ml FRESENIUS:

Jou dokter sal jou hartfunksie tydens die behandeling noukeurig moniteer, want:

DOXORUBICIN 2 mg/ml FRESENIUS kan die hartspier beskadig en kan tot hartversaking lei na 'n bepaalde kumulatiewe dosis (bymekaartel van enkelvoudige dosisse). Die risiko vir beskadiging van die hartspier is hoër as jy voorheen medisyne wat die hart kan beskadig, of bestraling van die bolyf ontvang het.

As jy hierdie behandeling ondergaan, sal jy gereeld EKG-monitering ondergaan en as jou dokter enige afwykings vind, sal hy/sy die behandeling staak of verdere evalueringstoetse doen.

Beenmurgonderdrukking met die toediening van DOXORUBICIN 2 mg/ml FRESENIUS:

Jy kan ly aan beenmurgonderdrukking ('n vermindering in beenmurgaktiwiteit wat lei tot 'n laer konsentrasie bloedplaatjies, rooibloedselle en witbloedselle). Dit kan jou meer vatbaar maak vir infeksies of bloeding.

Jou dokter sal gereeld bloedtoetse uitvoer om jou bloedselle te moniteer.

Ander veiligheidsinligting

DOXORUBICIN 2 mg/ml FRESENIUS kan die toksisiteit van ander antikankerbehandelings verhoog. Jou dokter sal seker maak dat die nodige toetse om hierdie effekte te moniteer gedoen word.

Die uriensuurvlakke (wat aantoon dat kankerselle vernietig word) in jou bloed kan tydens die behandeling hoog wees. Jou dokter sal jou inlig of jy nodig het om enige medisyne te neem om dit te beheer.

Bestaande infeksies moet behandel word voordat DOXORUBICIN 2 mg/ml FRESENIUS behandeling begin word.

DOXORUBICIN 2 mg/ml FRESENIUS word gewoonlik nie aanbeveel in kombinasie met lewende, verswakte entstowwe nie. Kontak met persone wat onlangs teen polio ingeënt is, moet vermy word.

Jy kan veranderinge in jou menstruele siklus ervaar en jou vermoë om swanger te word, kan beïnvloed word.

DOXORUBICIN 2 mg/ml FRESENIUS kan jou urien 'n rooi kleur gee, wat nie verkeerdelik as bloed geag moet word nie. Dit is 'n normale effek van die medisyne en hou nie gesondheidsgevare in nie.

Ander medisyne en DOXORUBICIN 2 mg/ml FRESENIUS

Lig altyd jou gesondheidsorgkundige in as jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Die volgende medisyne kan ’n interaksie hê met DOXORUBICIN 2 mg/ml FRESENIUS:

- ander kankermedisynes bv. trastusumab, antrasikliene (dounorubisien, epirubisien, idarubisien), sisplatien, siklofosfamied, siklosporien, sitarabien, dakarbasien, daktinomisien, fluoorurasiel, mitomisien C, taksaan (bv. paklitaksel), merkaptopurien, metotreksaat, streptososien, 6-merkaptopurien
- medisynes vir hartsiekte bv. kalsiumkanaalblokkers, verapamiel, en digoksien
- siklosporien ('n immuunonderdrukkende medisyne)
- ritonavir ('n medisyne gebruik vir MIV-behandeling)
- klosapien ('n antipsigotiese medisyne gebruik by skisofrenie)
- amfoterisien B (medisynes gebruik teen swamsiektes)

- uriensuur-verlagende medisynes (een voorbeeld is allopurinol), omdat hul dosis moontlik aangepas moet word
- radioterapie: enige radioterapie-behandeling voor, tydens en na DOXORUBICIN 2 mg/ml FRESENIUS kan die toksiese effekte op die hart en lewer verhoog
- lewende entstowwe (bv. polio (miëlitis), malaria)
- fenitoïen ('n medisyne gebruik om stuipe te voorkom en te beheer).

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 voordat jy DOXORUBICIN 2 mg/ml FRESENIUS ontvang.

Swangerskap

Jou dokter sal nie DOXORUBICIN 2 mg/ml FRESENIUS aan jou toedien as jy swanger is nie (kyk “Moenie DOXORUBICIN 2 mg/ml FRESENIUS gebruik nie”).

Borsvoeding

Moenie borsvoed terwyl jy met DOXORUBICIN 2 mg/ml FRESENIUS behandel word nie. Die medisyne kan deur die borsmelk aan die baba oorgedra word.

Vrugbaarheid

As jy 'n vrou is, moet jy nie swanger raak tydens behandeling met DOXORUBICIN 2 mg/ml FRESENIUS of tot 6 maande na behandeling nie.

As jy 'n man is, moet jy voldoende voorsorg tref om te verseker dat jou maat nie swanger raak tydens jou behandeling met DOXORUBICIN 2 mg/ml FRESENIUS, of tot 6 maande na die behandeling nie, en jy moet advies inwin oor krio-bewaring (of krio-preservering) van sperma voor behandeling vanweë die moontlikheid van

onomkeerbare onvrugbaarheid as gevolg van behandeling met DOXORUBICIN 2 mg/ml FRESENIUS. As jy dit oorweeg om na die behandeling ouers te word, bespreek dit asseblief met jou dokter.

Bestuur en gebruik van masjinerie

Naarheid en braking kom dikwels voor. As jy hierdie newe-effekte ervaar, moet jy vermy om motor te bestuur en masjinerie te gebruik terwyl jy met DOXORUBICIN 2 mg/ml FRESENIUS behandel word.

DOXORUBICIN 2 mg/ml FRESENIUS bevat natrium

DOXORUBICIN 2 mg/ml FRESENIUS bevat 0,15 mmol (3,5 mg) natrium per ml. As jy op 'n gekontroleerde natriumdieet is moet jy dit in ag neem.

3. Hoe om DOXORUBICIN 2 mg/ml FRESENIUS te gebruik

Daar sal nie van jou verwag word om DOXORUBICIN 2 mg/ml FRESENIUS aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen.

DOXORUBICIN 2 mg/ml FRESENIUS kan slegs onder toesig van 'n dokter met ervaring in kankerbehandeling gegee word.

Jou dokter sal jou dosis bereken volgens jou liggaamsoppervlakte, jou toestand en die kanker wat behandel moet word.

DOXORUBICIN 2 mg/ml FRESENIUS word binneaars toegedien (in 'n aar ingespuit). Die dosis sal herhaal word met tussenposes wat jou dokter bepaal. Jou dokter sal jou inlig hoe lank jou behandeling met DOXORUBICIN 2 mg/ml FRESENIUS sal aanhou.

Indien jy die indruk kry dat die effek van DOXORUBICIN 2 mg/ml FRESENIUS te sterk of te swak is, lig jou dokter in.

Indien jy meer DOXORUBICIN 2 mg/ml FRESENIUS ontvang het as wat jy moes:

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

Die simptome van oordosering sal 'n uitbreiding van die newe-effekte wees. Lig jou dokter in as enige van hierdie newe-effekte vir jou erger voel.

As jy vergeet om DOXORUBICIN 2 mg/ml FRESENIUS te gebruik

Aangesien 'n gesondheidsorgverskaffer DOXORUBICIN 2 mg/ml FRESENIUS sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

4. Moontlike newe-effekte

DOXORUBICIN 2 mg/ml FRESENIUS kan newe-effekte hê.

Nie alle newe-effekte wat vir DOXORUBICIN 2 mg/ml FRESENIUS aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak, of jy enige ongunstige effekte ondervind terwyl jy DOXORUBICIN 2 mg/ml FRESENIUS ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om DOXORUBICIN 2 mg/ml FRESENIUS te gebruik en lig jou dokter dadelik in, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van die hande, voete, gesig, lippe of keel, wat probleme om asem te haal kan veroorsaak,
- uitslag of jeuk, netelroos, rooi geswelde vel.

Hierdie is almal ernstige newe-effekte. Indien jy dit ervaar, kan jy moontlik 'n ernstige reaksie op DOXORUBICIN 2 mg/ml 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 (hoë temperatuur), kouekoors, bibbering en vinnige hartklop (sepsis, bloedvergiftiging)
- anemie ('n lae rooibloedseltelling) wat jou moeg en lusteloos kan laat voel
- lae bloedplaatjietelling wat jou makliker kan laat bloei of kneus
- lae aantal witbloedselle (hierdie selle beveg infeksie), wat die kans op infeksies en verhoogde temperatuur (koors) verhoog
- verminderde aktiwiteit in jou beenmurg, wat jou immuniteit teen infeksies beïnvloed. Jou dokter moet jou bloedtelling tydens die behandeling toets
- abnormale verhoging of onreëlmatige hartslag (kardiomiopatie, disritmie)
- kortasemigheid, geswelde bene (kongestiewe hartversaking)
- perforasie in die derms (bloed in die stoelgang, erge buikpyn, naarheid en braking van bloed)

- akute nierversaking (verminderde urinêre uitset, swelling van die bene, moegheid)
- pyn en swelling by die inspuitplek.

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

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

Gereelde newe-effekte:

- anoreksie
- naarheid
- braking
- geswelde of seer mond
- diarree
- haarverlies
- gesigsgloede

Minder gereelde newe-effekte

- dehidrasie (verlies aan water, dors gevoel)
- hoofpyn
- ooginfeksie
- uitermatige traanvorming
- lae bloeddruk
- inflammasie in die aar (flebitis)
- inflammasie van die slukderm (pyn met sluk)
- buikpyn

- sere in die derms en mond
- uitermatige pigmentasie van die vel en naels
- naels kom los
- urien kan rooi lyk
- jig (hoë uriensuur)
- afwesigheid van menstruasie
- verminderde sperm-volume
- vergrote borste
- voel ongesteld
- swakheid
- koue rillings
- duiseligheid

Frekwensie onbekend:

- tromboëmbolisme (klontvorming in 'n bloedvat)
- oormatige pigmentasie van die mondslymvlies - gevoel van intense hitte (warmgloede)
- inflammasie van die dikderm (kolitis)
- lewersiektes (geel verkleuring van die vel en oë, verhoogde lewerensieme met bloedtoetse)
- weefsel hipoksie (lae suurstof in jou weefsels) (jou vel kan koud voel en indien ernstig 'n blouerige kleur kry)

- plantare-palmare disestesie (hand-voet-sindroom is 'n kenmerkende en relatiewe gereelde toksiese reaksie van die vel)
- fotosensitiwiteit
- geen spermvorming nie
- astenie (verlies of gebrek aan liggaamskrag; swakheid; debiliteit)
- tromboflebitis (inflammasie van 'n aar onder die vel)
- 'n prikkelende of branderige gevoel op die toedieningsplek, veroorsaak deur uitsyfering. Ekstravasasie kan lei tot plaaslike afsterwing van die weefsel, waarvoor chirurgiese maatreëls nodig kan wees.

Indien jy enige newe-effekte waarneem wat nie in hierdie pamflet vermeld word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte

Indien jy enige newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn onder SAHPRA se publikasies verskyn: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld kan jy help om meer inligting rakende die veiligheid van DOXORUBICIN 2 mg/ml FRESENIUS te verskaf.

5. Hoe om DOXORUBICIN 2 mg/ml FRESENIUS te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar teen 2-8 °C. Moenie vries nie. Hou die flessie in die karton om dit teen lig te beskerm. Bewaar in die regop posisie.

Voorbereiding van die infusie:

DOXORUBICIN 2 mg/ml FRESENIUS is slegs vir enkele gebruik. Alle ongebruikte oplossing moet weggegooi word.

Na verdunning met 0,9 % natriumchloried of dekstrose 5 % in water moet die verdunde oplossing dadelik gebruik word. Alle ongebruikte oplossing moet weggegooi word.

6. Inhoud van die pakkie en ander inligting

Wat DOXORUBICIN 2 mg/ml FRESENIUS bevat

- Die aktiewe bestanddeel is doksorubisienhidrochloried. Elke ml van die konsentraat vir oplossing vir infusie bevat 2 mg doksorubisienhidrochloried.

Elke 5 ml flessie bevat 10 mg doksorubisienhidrochloried.

Elke 25 ml flessie bevat 50 mg doksorubisienhidrochloried.

- Die ander bestanddele is natriumchloried en water vir inspuiting.

Hoe DOXORUBICIN 2 mg/ml FRESENIUS lyk en wat die inhoud van die pakkie is

DOXORUBICIN 2 mg/ml FRESENIUS is 'n helderrooi oplossing, gevul in 'n deursigtige glasflessie; wanneer dit onder geskikte sigbaarheidstoestande ondersoek word moet dit vry wees van deeltjies.

DOXORUBICIN 10 mg/5 ml FRESENIUS is verpak in 'n deursigtige kleurlose tipe I glasflessie van 5 ml met 'n inhoud van 5 ml, toegemaak met 'n grys broombutielprop met 'n aluminium afwip-verseëling.

Elke flessie kan saam met 'n plastiekbodem met krimpblad toegedraai word en in 'n enkele karton verpak word.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

DOXORUBICIN 50 mg/25 ml FRESENIUS is verpak in 'n deursigtige kleurlose tipe I glasflessie van 30 ml met 'n inhoud van 25 ml, toegemaak met 'n grys broombutielprop met 'n aluminium afwip-verseëling.

Elke flessie kan saam met 'n plastiekbodem met krimpfoelie toegedraai word en in 'n enkele karton verpak word.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die registrasiesertifikaat

Fresenius Kabi South Africa (Pty) Limited

Erf 7, Growthpoint Business Park

Tonettistraat 2

Midrand, Suid-Afrika

Hierdie pamflet was voorheen hersien in

Registrasienommers

Doxorubicin 10 mg/5 ml Fresenius: 48/26/0937

Doxorubicin 50 mg/25 ml Fresenius: 48/26/0938

Toegang tot die ooreenstemmende professionele inligting

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