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1.3.1 spc-label-pl - common-pl - 3,513 (AT/H/0256-0257/IB/008, IB/004 2. Response)		20130806
IRINOTECAN HYDROCHLORIDE 20 MG / 1 ML CONCENTRATE FOR SOLUTION FOR INFUSION		722-0334.00

PACKAGE LEAFLET: INFORMATION FOR THE USER

Irinotecan Ebewe 20 mg/ml concentrate for solution for infusion

Irinotecan hydrochloride trihydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Irinotecan Ebewe is and what it is used for
2. What you need to know before you use Irinotecan Ebewe
3. How to use Irinotecan Ebewe
4. Possible side effects
5. How to store Irinotecan Ebewe
6. Contents of the pack and other information

1. What Irinotecan Ebewe is and what it is used for

Irinotecan Ebewe belongs to a group of medicines called cytostatics (anti-cancer medicines).

Irinotecan Ebewe is used for the treatment of advanced cancer of the colon and rectum in adults, either in a combination with other medicines (i.e. 5-fluorouracil/folinic acid, bevacizumab, cetuximab, capecitabine), or alone.

2. What you need to know before you use Irinotecan Ebewe

Do not use Irinotecan Ebewe

- if you are allergic (hypersensitive) to irinotecan hydrochloride trihydrate or any of the other ingredients of Irinotecan Ebewe
- if you have any other bowel disease or a history of bowel obstruction
- if you are breast feeding
- if you have increased levels of bilirubin in the blood (more than 3 times the upper limit of normal)
- if you have severe bone marrow failure
- if you are in a poor general health (evaluated by an international standard)
- if you are using the natural remedy St Johns' Wort (*Hypericum perforatum*)

You must not get yellow fever vaccine during during therapy with Irinotecan Ebewe

About additional contraindications of cetuximab, bevacizumab or capecitabine please read the product information of these medicines.

Warnings and precautions

This medicine is intended for adults only. Check with your doctor if this medicine has been prescribed for use in a child.

Special care is also needed in elderly patients.

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As Irinotecan Ebewe is an anti-cancer medicine it will be administered to you in a special unit and under the supervision of a doctor qualified in the use of anti-cancer medicines. The unit's personnel will explain to you what you need to take special care of during and after the treatment. This leaflet may help you to remember that.

1) *The first 24 hours after administration of Irinotecan Ebewe*

During administration of Irinotecan Ebewe (30-90 min.) and shortly after administration you may experience some of the following symptoms:

- diarrhoea
- sweating
- abdominal pain
- watering eyes
- visual disturbance
- excessive mouth watering

The medical term for these symptoms is acute cholinergic syndrome which can be treated (with atropine). If you have any of these symptoms immediately tell your doctor who will give you any treatment necessary.

2) *From the day after treatment with Irinotecan Ebewe until next treatment*

During this period you may experience various symptoms, which may be serious and require immediate treatment and close supervision.

- **Diarrhoea**

If your diarrhoea starts more than 24 hours after administration of Irinotecan Ebewe ("delayed diarrhoea") it may be serious. It is often seen about 5 days after administration. The diarrhoea should be treated immediately and kept under close supervision. Immediately after the first liquid stools do the following:

1. Take any anti-diarrhoeal treatment that the doctor has given you, exactly as he/she has told you. The treatment may not be changed without consulting the doctor. Recommended anti-diarrhoeal treatment is loperamide (4 mg for the first intake and then 2 mg every 2 hours, also during the night). This should be continued for at least 12 hours after the last liquid stools. The recommended dosage of loperamide may not be taken for more than 48 hours.
2. Drink large amounts of water and rehydration fluids, immediately (i.e. water, soda water, fizzy drinks, soup or oral rehydration therapy).
3. Immediately inform your doctor who is supervising the treatment, and tell him/her about the diarrhoea. If you are not able to reach the doctor, contact the unit at the hospital supervising the Irinotecan Ebewe treatment. It is very important that they are aware of the diarrhoea.

You must immediately tell the doctor, or the unit supervising the treatment, if

- **you have nausea and vomiting as well as diarrhoea**
- **you have any fever as well as the diarrhoea**
- **you still have diarrhoea 48 hours after starting the diarrhoea treatment**

Note! Do not take any treatment for diarrhoea other than that given to you by your doctor and the fluids described above. Follow the doctor's instructions. The anti-diarrhoeal treatment should **not** be used to prevent a further episode of diarrhoea, even though you have experienced delayed diarrhoea at previous cycles.

- **Fever**

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If the body temperature increases over 38°C it may be a sign of infection, especially if you also have diarrhoea. If you have any fever (over 38°C) contact your doctor or the unit immediately so that they can give you any treatment necessary.

- **Nausea and vomiting**

If you have nausea and/or vomiting contact your doctor or the unit immediately.

- **Neutropenia**

Irinotecan Ebewe may cause a decrease in the number of some of your white blood cells, which play an important role in fighting infections. This is called neutropenia. Neutropenia is often seen during treatment with

Irinotecan Ebewe and is reversible. Your doctor should arrange for you to have regular blood tests to monitor these white blood cells. Neutropenia is serious and should be treated immediately and carefully monitored.

- **Breathing difficulties**

If you have any breathing difficulties contact your doctor immediately.

- **Impaired liver function**

Before treatment with Irinotecan Ebewe is started and before every following treatment cycle the liver function should be monitored (by blood tests).

If you have one or more of the symptoms mentioned, after you have returned home from the hospital, you should immediately contact the doctor or the unit supervising the Irinotecan Ebewe treatment.

- **Impaired kidney function**

As this medicine has not been tested in patients with kidney problems, please check with your doctor if you have any kidney problems.

- **Heart problems**

Heart attacks have been observed following treatment with Irinotecan Ebewe. If you have any heart disease, known risk factors for heart disease, or previous cytotoxic chemotherapy your doctor will monitor you closely. Action should be taken to try to minimize all modifiable risk factors for heart problems (e.g. smoking, high blood pressure, and high level of fat in the blood).

- **Infections**

You might get serious infections or face reduced response to vaccinations during therapy with Irinotecan Ebewe. Your doctor will try to avoid vaccinations during therapy with Irinotecan Ebewe.

Other medicines and Irinotecan Ebewe

Please tell your doctor if you are taking or have recently taken any other medicines., This is also valid for herbal medicines, strong vitamins and minerals.

Some medicines may alter the effects of Irinotecan Ebewe e.g. ketoconazole (for the treatment of fungal infections), rifampicin (for the treatment of tuberculosis), atazanavir sulphate (for the treatment of HIV-1) and some medicines for the treatment of epilepsy (carbamazepine, phenobarbital and phenytoin).

The herbal medicine St John's Wort (*Hypericum perforatum*) must not be used concurrent with Irinotecan Ebewe and not between treatments, as it may decrease the effect of irinotecan.

If you require an operation, please tell your doctor or anaesthetist that you are using this medicine, as it may alter the affect of some medicines used during surgery.

You must not get yellow fever vaccine during during therapy with Irinotecan Ebewe. Tell your doctor that you are using this medicine if you require any other vaccine, as this might result in side effects.

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If you receive Irinotecan Ebewe in combination with a medicinal product containing cetuximab, bevacizumab, cyclosporine, tacrolimus or capecitabine, please make sure that you also read the package inserts for those products.

Pregnancy

You should not receive Irinotecan Ebewe during pregnancy, especially during the first trimester, unless clearly necessary..

Women of child-bearing age should avoid becoming pregnant. Contraceptive measures must be taken by both male and female patients during and for at least three months after cessation of therapy. Still, if you become pregnant, think you could be pregnant, or could become pregnant during this period you must immediately inform your doctor.

Breast-feeding

It is not known whether Irinotecan Ebewe is excreted in human milk. Consequently, you must not breast-feed while you are treated with Irinotecan Ebewe .

Driving and using machines

In some cases Irinotecan Ebewe may cause side effects which affect the ability to drive and use tools and machines. Contact your doctor or pharmacist if you are unsure.

During the first 24 hours after administration of Irinotecan Ebewe you may feel dizzy or have visual disturbances. If this happens to you do not drive or use any tools or machines.

Irinotecan Ebewe contains sorbitol. If you suffer from **intolerance to some sugars**, tell your doctor before you are given this medicinal product.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium- free’.

3. How to use Irinotecan Ebewe

Irinotecan Ebewe will be given as an infusion into your veins over a period of 30-90 minutes. The amount of infusion you are given will depend on your age, size and general medical condition. It will also depend on any other treatment you may have received for your cancer. Your doctor will calculate your body surface area in square meters (m²).

- If you have previously been treated with 5-fluorouracil you will normally be treated with Irinotecan Ebewe alone starting with a dose of 350 mg/m² every 3 weeks.
- If you have not had previous chemotherapy you will normally receive 180 mg/m² Irinotecan Ebewe every two weeks. This will be followed by folinic acid and 5-fluorouracil.
- If you are treated with Irinotecan Ebewe in combination with cetuximab you will normally receive the same dose of irinotecan as administered in the last cycles of the prior irinotecan containing regimen.

Irinotecan Ebewe must not be administered earlier than 1 hour after the end of the cetuximab infusion.

If you receive Irinotecan Ebewe in combination with cetuximab, please consult the cetuximab leaflet.

If you receive Irinotecan Ebewe in combination with bevacizumab, please consult the bevacizumab leaflet.

If you receive Irinotecan Ebewe in combination with capecitabine, please consult the capecitabine leaflet.

These dosages may be adjusted by your doctor depending on your condition and any side-effects you may have.

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4. Possible side effects

Like all medicines, Irinotecan Ebewe this medicine can cause side effects, although not everybody gets them. Your doctor will discuss these side effects with you and explain the risks and benefits of your treatment.

Some of these side effects must be treated **immediately**, see also information in section “Warnings and precautions”.

Diarrhoea

Irinotecan Ebewe may cause you to have diarrhoea. There are two types of diarrhoea, which can be distinguished when they start. “Early” diarrhoea starts less than 24 hours after the infusion and “delayed” diarrhoea starts more than 24 hours after infusion of Irinotecan Ebewe .

If you have **ANY DIARRHOEA** it is **IMPORTANT** that you follow these instructions carefully.

Early diarrhoea

If your diarrhoea starts less than 24 hours after the infusion, you should contact your health care team immediately and they will give you a suitable treatment.

This early diarrhoea might be accompanied by other symptoms such as

- abdominal pain
- red, sore, itching or watering eyes
- running nose
- low blood pressure
- sweating
- chills
- dizziness
- visual disturbance
- pupils of the eye get smaller
- excessive mouth watering
- a feeling of general discomfort and illness

Do not use any anti-diarrhoeal treatment that your doctor has given you for “delayed diarrhoea”.

Delayed diarrhoea

If your diarrhoea starts more than 24 hours after infusion (often about 5 days after administration), **immediately** take any anti-diarrhoeal treatment that the doctor has given you, **exactly as he/she has told you**.

If you are unsure of what it is, ask your doctor or healthcare team. The treatment may not be changed without consulting the doctor.

Drink large amounts of water and rehydration fluids, **immediately** (i.e. water, soda water, fizzy drinks, soup or oral rehydration therapy).

Immediately inform your doctor who is supervising the treatment, and tell him/her about the diarrhoea. If you are not able to reach the doctor, contact the unit at the hospital supervising the Irinotecan Ebewe treatment. It is very important that they are aware of the diarrhoea.

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You must immediately tell the doctor, or the unit supervising the treatment, if

- **you have nausea and vomiting as well as diarrhoea**
- **you have any fever as well as the diarrhoea**
- **you still have diarrhoea 48 hours after starting the diarrhoea treatment**

Do not take any treatment for diarrhoea other than that given to you by your doctor and only drink the fluids described above.

Decrease in white blood cells

Irinotecan Ebewe may cause a decrease in the number of some of your white blood cells, which play an important role in fighting infections. This is called neutropenia. Neutropenia is often seen during treatment with

Irinotecan Ebewe and is reversible. Your doctor should arrange for you to have regular blood tests to monitor these white blood cells. Neutropenia is serious and should be treated immediately and carefully monitored.

If you have any **fever** (body temperature increases over 38°C), this may be a sign of an infection associated with neutropenia and requires immediate treatment.

If you have any fever (over 38°C) and especially if you also have diarrhoea, contact your doctor or the unit **immediately** so that they can give you any treatment necessary.

Nausea and vomiting

If you have nausea and/or vomiting contact your doctor or the unit **immediately**.

Breathing difficulties

If you have any breathing difficulties contact your doctor **immediately**.

Allergic reactions

All drugs can cause allergic reactions. If you experience any of the following symptoms contact your doctor or the unit **immediately**.

- swelling of the of the hands, feet, ankles, face, lips, mouth or throat
- difficulty in swallowing or extreme difficulty breathing
- you may feel like you are going to faint

Other side effects which may occur are:

Very common side effects (affects more than 1 user in 10):

- Decreased number of red blood cells (anaemia), which can make the skin pale and cause weakness and breathlessness.
- Decreased number of blood platelets (thrombocytopenia) causing bruises and tendency to bleed when Irinotecan Ebewe is given in combination with other agents
-
- Hair loss (the hair grows again after end of treatment).
- increase in serum levels of some enzymes (SGPT, SGOT, alkaline phosphatase) or bilirubin when Irinotecan Ebewe is given in combination with other agents

If you receive Irinotecan Ebewe in combination with capecitabine , blood clots may occur.

Common side effects(affects 1 to 10 users in 100):

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- Irinotecan Ebewe Decreased number of blood platelets (thrombocytopenia) causing bruises and tendency to bleed when Irinotecan Ebewe is given alone Loss of water (dehydration), commonly associated with diarrhoea and /or vomiting.
- Constipation.
- Feeling weak (asthenia).
- increase in serum levels of some enzymes (SGPT, SGOT, alkaline phosphatase) or bilirubin when Irinotecan Ebewe is given alone
- severe increase in serum levels of bilirubin when Irinotecan Ebewe is given in combination with other agents
- mild to moderate increase in levels of creatinine in the blood.

If you receive Irinotecan Ebewe in combination with capecitabine, allergic reactions, heart attack and fever in patients with a low white cell blood count may occur. If you receive Irinotecan Ebewe in combination with capecitabine and bevacizumab, low white blood cell count, blood clots, high blood pressure and heart attack may occur.

Uncommon side effects (affects 1 to 10 users in 1,000):

- Mild allergic skin reactions (red itchy skin, rash),
- mild reactions at the infusion site (redness).
- Difficulty in breathing and dry cough Partial or complete blockage of the bowel (intestinal obstruction, ileus).
- Vomiting blood (gastrointestinal bleeding)
- Bowel inflammation, causing abdominal pain and/or diarrhoea (a condition known as pseudomembraneous colitis).
- Kidney problems, and low blood pressure associated with diarrhoea and/or vomiting or infection.

Rare side effects (affects 1 to 10 users in 10,000):

- muscular cramps and numbness (pins and needles).
- abdominal pain (inflammation of the large bowel).
- Intestinal perforation (a “hole” in the bowel)
- loss of appetite (anorexia)
- inflammation of the pancreas (may cause abdominal pain).
- Increased blood pressure during and following administration.
- Decreased levels of potassium and sodium in the blood, mostly related to diarrhoea and vomiting.

Very rare side effects (affects less than 1 user in 10,000):

- speech disorders (goes away when treatment is stopped)
- Increase in levels of some digestive enzymes which break down sugars and fats.
- One case of low platelet count in the blood due to antibodies against platelets was reported.

If you receive Irinotecan Ebewe in combination with a medicine containing cetuximab, bevacizumab or capecitabine, some of the side effects you may experience can also be related to these combination. Such side effects may include an acne-like rash. Therefore, please make sure that you also read the package leaflet for cetuximab, bevacizumab or capecitabine.

Reporting of side effects

If you get any side effects, talk to your doctor or healthcare team. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

REPORTING OF SIDE EFFECTS

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You can report a suspected side effect in a number of ways: •To your doctor, pharmacist or nurse who can then notify the IMB.

•By using the IMB's online form. A downloadable version of the form is also available, which can be filled in manually and sent to the IMB by freepost.

•By calling the IMB on (01) 676 4971.

5. How to store Irinotecan Ebewe

Keep out of the sight and reach of children.

For single use only.

Before opening

Keep the vial in the outer carton in order to protect from light.

Do not use this medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

After opening

The product should be diluted and used immediately after opening.

After dilution

From a microbiological point of view, the product should be used immediately after dilution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally be not longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Chemical and physical in-use stability have been demonstrated for 28 days at 2-8°C as well as at room temperature (20-25°C) with light protection and for 48 hours without light protection.

Do not use Irinotecan Ebewe if you notice particles in the solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Irinotecan Ebewe contains

- The active substance is irinotecan hydrochloride trihydrate.
- One ml of concentrate contains 20 mg irinotecan hydrochloride trihydrate equivalent to 17.33 mg of irinotecan.
- One 2ml vial contains 40 mg irinotecan hydrochloride trihydrate.
- One 5ml vial contains 100 mg irinotecan hydrochloride trihydrate.
- One 7.5ml vial contains 150 mg irinotecan hydrochloride trihydrate.
- One 15ml vial contains 300 mg irinotecan hydrochloride trihydrate.
- One 25ml vial contains 500 mg irinotecan hydrochloride trihydrate.
- The other ingredients are sorbitol E420, lactic acid, sodium hydroxide and water for injections

What Irinotecan Ebewe looks like and contents of the pack

Amber class I glass vial with rubber stopper (fluoropolymer coated bromobutyl rubber stopper), with or without a protective plastic overwrap (Onco-Safe). "Onco-Safe" does not come into contact with the medicinal product and provides additional transport protection, which increases the safety for the medical and pharmaceutical personnel.

The vials are sealed with aluminium crimp caps.

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Clear, colourless to slightly yellow solution.

Pack sizes:

40 mg/2 ml: 1 vial, 5 vials, 10 vials
100 mg/5 ml: 1 vial, 5 vials, 10 vials
150 mg/7.5 ml: 1 vial, 5 vials, 10 vials
300 mg/15 ml: 1 vial
500 mg/25 ml: 1 vial

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Ebewe PharmaGes.m.b.HNfg.KG
Mondseestrasse11
4866Unterach
Austria

Manufacturer: AT/H/0256/001:

EBEWE Pharma Ges.m.b.H. Nfg. KG
Mondseestraße 11, A-4866 Unterach,
Austria

Manufacturer: AT/H/0257/001:

EBEWE Pharma Ges.m.b.H. Nfg. KG
Mondseestraße 11, A-4866 Unterach,
Austria

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
39179 Barleben
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

AT/H/0256/001:

Austria	Irinoliquid 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Irinotecan Sandoz 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung Irinotecan Sandoz 20 mg/ml solution à diluer pour perfusion Irinotecan Sandoz 20 mg/ml concentraat voor oplossing voor intraveneuze infusie
Bulgaria	Irinotecan Ebewe 20 mg/ml концентрат за инфузионен разтвор
Cyprus	Irinotecan Ebewe 20 mg/ml Πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Czech Republic	Irinotecan Ebewe 20 mg/ml koncentrát pro přípravu infuzního roztoku
Denmark	Irinotecan "Ebewe", koncentrat til infusionsvaeske, opløsning
Estonia	Irinotecan Ebewe 20 mg/ml infusioonilahuse kontsentraat 20mg/ml

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Finland	Irinotecan Ebewe 20 mg/ml infuusiokonsentraatti, liuosta varten
France	Irinotecan Ebewe 20 mg/ml, solution à diluer pour perfusion
Germany	Irino-NC 20mg/ml
Greece	Irinotecan Ebewe 20mg/ml Πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Hungary	Irinotecan Ebewe 20 mg/ml koncentrátum oldatos infúzióhoz
Ireland	Irinotecan Ebewe 20 mg/ml concentrate for solution for infusion
Italy	Irinotecan Sandoz GmbH
Latvia	Irinotecan Ebewe 20 mg/ml koncentrāts infūziju šķīduma pagatavošanai
Lithuania	Irinotecan Ebewe 20 mg/ml koncentratas infuziniam tirpalui
Luxembourg	Irinotecan Sandoz 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Malta	Irinotecan Ebewe 20 mg/ml concentrate for solution for infusion
Netherlands	Irinotecan HCL-trihydraat Sandoz 20 mg/ml concentraat voor oplossing voor infusie
Norway	Irinotecan Ebewe 20 mg/ml konsentrat til infusjonsvæske
Poland	Irinotecan - Ebewe
Portugal	Irinotecano Sandoz 20mg/ml concentrado para solução para perfusão
Romania	Irinotecan "Ebewe" 20mg/ml concentrat pentru soluție perfuzabilă
Slovakia	Irinotecan Ebewe 20 mg/ml infúzny koncentrát
Slovenia	Irinotekan Ebewe 20mg/ml koncentrat za raztopino za infundiranje
Spain	Irinotecán Ebewe 20 mg/ml concentrado para solución para perfusión
Sweden	Irinotecan Ebewe 20mg/ml koncentrat till infusionsvätska, lösning
United Kingdom	Irinotecan 20mg/ml concentrate for solution for infusion

AT/H/0257/001:

Austria	Eberino 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Germany	Irinotecan HEXAL 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung

This leaflet was last approved in 09/2013

The following information is intended for healthcare professionals only:

Instruction for use

Cytotoxic

Handling of Irinotecan Ebewe

As with all antineoplastic agents, caution should be exercised when handling Irinotecan Ebewe . Dilution should be carried out under aseptic conditions by trained personnel in a designated area. Precautions should be taken to avoid contact with the skin and mucous membranes.

Protection instructions for preparation of Irinotecan Ebewe solution for infusion

1. Protective chamber should be used and protective gloves as well as protective gown should be worn. If there is no protective chamber available mouth cover and goggles should be used.
 2. Opened containers, like injection vials and infusion bottles and used cannulae, syringes, catheters, tubes, and residuals of cytostatics should be considered as hazardous waste and undergo disposal according to local guidelines for the handling of HAZARDOUS WASTE.
 3. Follow the instructions below in case of spillage:
 - protective clothing should be worn
 - broken glass should be collected and placed in the container for HAZARDOUS WASTE
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- contaminated surfaces should be flushed properly with copious amounts of cold water
- the flushed surfaces should then be wiped thoroughly and the materials used for wiping should be disposed as HAZARDOUS WASTE

4. In the event of Irinotecan Ebewe contact with the skin, the area should be rinsed with plenty of running water and then washed with soap and water. In case of contact with mucous membranes, wash the contacted area thoroughly with water. If you have any discomfort, contact a doctor.
5. In case of contact of Irinotecan Ebewe with eyes, wash them thoroughly with plenty of water. Contact an ophthalmologist immediately.

Preparation of infusion solution

Irinotecan Ebewe concentrate for solution for infusion is intended for intravenous infusion only after diluting prior to administration in the recommended diluents, either 0.9 % Sodium chloride solution for infusion or 5% glucose solution for infusion. Aseptically withdraw the required amount of Irinotecan Ebewe concentrate for solution from the vial with a calibrated syringe and inject into a 250 ml infusion bag or bottle. The infusion should be thoroughly mixed by manual rotation.

If any precipitate is observed in the vials or after reconstitution, the product should be discarded according to standard procedures for cytotoxic agents.

Read the package leaflet for the shelf life of the diluted product.

Irinotecan Ebewe should **not** be delivered as an intravenous bolus or an intravenous infusion shorter than 30 minutes or longer than 90 minutes.

Disposal

All items used for preparation, administration or otherwise coming into contact with irinotecan should undergo disposal according to local guidelines for the handling of cytotoxic compounds.