Package leaflet: Information for the user

onivy® pegylated liposomal 4.3 mg/ml concentrate for solution for infusion

Read all of this leaflet carefully before you start using this medicine and save it for future reference.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or nurse.

If you get any side effects, talk to your doctor or nurse.

This leaflet does not contain all the available information. Side effects not listed in this leaflet. See section 4.

1. What onivy® pegylated liposomal is and what it is used for

What onivy® pegylated liposomal is and how it works

ONIVY® pegylated liposomal is a medicine that contains camptothecin, a type of anticancer medicine, which is involved in the division of cancer cells. This prevents the cancer cells from multiplying and growing, and they eventually die.

ONIVY® pegylated liposomal is expected to work in the body by interacting with the cell surface of cancer cells. In doing so, ONIV® pegylated liposomal may stop the cancer cells from multiplying.

What ONIV® pegylated liposomal is used for

ONIV® pegylated liposomal is used to treat certain cancers in adults. ONIV® pegylated liposomal is used to treat:

- cancer of the lungs
- certain cancers of the cervix (neck of the womb)

What ONIV® pegylated liposomal contains

- Active substance: camptothecin
- Excipients: a combination of liposomes and polyethylene glycol

How to take ONIV® pegylated liposomal

- admin. route: intravenous administration
- admin. site: large veins
- admin. duration: 1-hour infusion

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. It is important that you are aware of these side effects.

Your doctor may also prescribe other medicines to help control your side effects.

Talk to your doctor or nurse about any of the following serious side effects:

- if you experience sudden shortness of breath, flushing, nausea, vomiting, or dizziness (with or without rash on the skin) (all of which may be signs of an allergic reaction possibly including anaphylaxis)

- if you get hives, swelling of the lips, mouth, or throat, difficulty in swallowing or breathing

- if you have severe persistent diarrhoea (bright and frequent and accompanied by vomiting)

The following side effects may occur:

- ulcers in the mouth and nose
- tiredness
- cold symptoms

- mild skin reactions

In the event of an allergic reaction, you should stop treatment and seek medical advice immediately.

5. How to store ONIV® pegylated liposomal

This medicine should only be given by healthcare professionals trained in giving antinecancer medicines. Please keep this leaflet and talk to your doctor or nurse before you start using this medicine. Your doctor will discuss the doses you will receive.

You may receive a combination of liposomes and polyethylene glycol as a liposome. A liposome may be used to store an active substance so that it may be given as a single injection. After you have been given ONIV® pegylated liposomal, you will be discharged home with instructions on how to continue treatment. This may include:

- taking other medicines
- eating certain foods

ONIV® pegylated liposomal contains sodium and potassium.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Further blood or other tests during treatment so that your doctor can monitor your blood cells and assess how you are responding to the treatment. Your doctor may need to adjust the dose or stop treatment.

Other medicines and ONIV® pegylated liposomal

Talk to your doctor or nurse, taking into account what you are taking other medicines.

It is especially important that you tell your doctor if you have been given blood transfusions in any form earlier.

ONIV® pegylated liposomal is not recommended for use in children and infants below the age of 18 years.

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6. Contents of the pack and other information

What ONYVYE®-pegolysed iposomal contains:

- The active substance is fosmideron. One 10 ml vial of concentrate contains 25 mg of the active substance (acyclovir sodium) in a pegolysed (iposomal) formulation.
- The other ingredients are: 1,2-dimyristoyl-sn-glycero-3-phosphocholine (DMPC), cholesterol, 4-carboxy-methoxypoloxylglycerol-2000, 1,2-distearoyl-sn-glycerol-3-phosphoethanolamine (DTES-2000-30TPE), ricinoleic acid (50%), N, N-diethyltoluamide (DEET) and water for injections. ONYVYE®-pegolysed iposomal contains sodium, if you are on a sodium restricted diet see section 4.2.

What ONYVYE®-pegolysed iposomal looks like and contents of the pack:

ONYVYE®-pegolysed iposomal is supplied as a white or slightly yellow, opalescent iposomal dispersion in a glass vial.

Each pack contains one vial with 10 ml of concentrate.

Marketing Authorisation Holder

Inte Laboratories S.R.L.

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Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last revised in 04/2019

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

The following information is intended for healthcare professionals only:

How to prepare and administer ONYVYE®-pegolysed iposomal:

ONYVYE®-pegolysed iposomal is supplied as a lyophilised iposomal dispersion at a concentration of 4.8 mg/ml and must be diluted prior to administration. Dilute with 5% glucose solution for injection or sodium chloride 0.9 mg/ml (0.9%) solution for injection to prepare a suspension of the appropriate dose of ONYVYE®-pegolysed iposomal diluted to a final volume of 50 ml. Mix well and refrigerate by gentle inversion.

ONYVYE®-pegolysed iposomal should be administered (before sugar-free honey or D-glucose) ONYVYE®-pegolysed iposomal must not be administered as a bolus injection or an undiluted solution.

Aseptic technique must be followed during the preparation of the injection. ONYVYE®-pegolysed iposomal is for single use only.

After microbiological point of view the product should be used as soon as possible after dilution. The diluted solution for injection can be stored at ambient temperature (15°C to 30°C) for up to 4 hours or in the refrigerator (2°C to 8°C) for no more than 24 hours prior to use. It must be protected from light, and it must not be frozen.

Care should be taken to avoid extravasation, and the injection site should be monitored for signs of inflammation. Solution and needles should be discarded after use with sodium chloride 0.9 mg/ml (0.9%) solution for injection and sterile water are applications of use are recommended.

How to handle and dispose of ONYVYE®-pegolysed iposomal:

ONYVYE®-pegolysed iposomal is a cytotoxic medicinal product and caution should be exercised in handling. The use of gloves, protective glasses and protective clothing when handling or administering ONYVYE®-pegolysed iposomal is recommended. If the solution contacts the skin, the skin should be washed immediately and thoroughly with soap and water. The solution should be discarded if it is accidentally splashed into the eye. It is used in the treatment of varicella zoster, including the ophthalmic form of the disease, and should preferably be disposed of in accordance with local recommendations.

ONYVYE®-pegolysed iposomal is a cyclic derivative of acyclovir considering the cytidine nucleus of the medicinal product.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.