Patient Information Leaflet

Idarubicin 5 mg/5 ml solution for injection
Idarubicin 10 mg/10 ml solution for injection
Idarubicin 20 mg/20 ml solution for injection
Idarubicin (hydrochloride)

Read all of this leaflet carefully before you are given 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 or pharmacist.
- 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.

What is in this leaflet:

1. What Idarubicin Injection is and what it is used for

Idarubicin Injection belongs to a group of medicines called as citotoxics and antimitotics agents, which intercalate with DNA and interact with topoisomerase II, having an inhibitory effect on the synthesis of nucleic acid.

Idarubicin Injection is a medicine used for the treatment :

Adults
-Acute non-lymphocytic leukaemia, for remission induction in untreated patients or for remission induction in relapsed or refractory patients.
-Acute lymphocytic leukaemia as second line treatment.

Children
-Acute non-lymphocytic leukaemia, in combination with cytarabine, for remission induction in untreated patients.
-Acute lymphocytic leukaemia as second line treatment.

Idarubicin Injection may also be used in combination with other anticancer agents.

2. What you need to know before you are given Idarubicin Injection

Do not take Idarubicin Injection:
- if you are allergic to idarubicin or to any of the other ingredients in this medicine (listed in section 6);
- if you are allergic to other anthracyclines or anthracenediones;
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- if you suffer from severe liver problems ;
- if you suffer from sever kidneys problems;
- if you suffer from heart problems;
- if you have low production of blood cells and platelets;
- If you have previously been treated with idarubicin and/ or other anthracyclines or anthracenediones.
- If you are breast-feeding.

Warnings and Precautions
- if you have heart trouble. Heart function must be assessed before starting treatment with idarubicin and must be monitored during treatment to minimise the risk of incurring severe heart failure;
- if you have a reduced bone marrow blood cell and platelet count;
- if you have a marked and permanent increase of abnormal white cells in the blood. You may be developing leukaemia;
- if you have gastrointestinal problems;
- if you have liver problems;
- if you have kidney problems;
- this medicine can cause vomiting, may develop inflammation of the oral mucosa or inflammation of the mucosal lining of the digestive tract;
- you may develop reactions at the injection site;
- if extravasation occurs during the injection, you may feel pain and extravasation may cause severe tissue lesions. If extravasation occurs, administration of the medicine must be discontinued immediately;
- as happens with other cytotoxic agents, inflammation of a vein wall may occur, with the formation of blood clots;
- if you have recently had or are thinking of having a vaccine;
- if you are a man, idarubicin can cause irreversible infertility.

Idarubicin must be administered only under the supervision of a doctor with experience in cytotoxic chemotherapy.

This medicine can cause red colouration of urine for one to two days after its administration.

Before and during the treatment with Idarubicin Injection, regular exams should be made to the blood, liver, kidneys and heart. Babies and children seem to have a greater sensitivity to cardiac toxicity induced by anthracyclines. Thus, in these patients, it is necessary to do regular examination to the heart for a long period of time.

Other medicines and Idarubicin Injection
Tell your doctor if you are taking, have recently taken, or might take any other medicines.

Idarubicin is used mainly in association with other cytotoxic agents, and additive toxicity may occur, especially with regard to bone marrow, blood and gastrointestinal. The risk of cardiac toxicity may increase in patients who have received at the same time other medicines with toxic properties to the heart.
Since idarubicin is extensively metabolised by the liver, impairments in liver function caused by other medicines may affect idarubicin metabolism, pharmacokinetics and therapeutic efficacy and/ or toxicity.

Anthracyclines, including idarubicin, must not be administered in association with other cardiotoxic agents, unless heart function is carefully monitored.

In the case of association of oral anticoagulants and anticancer chemotherapy, greater frequency in monitoring the International Normalised Ratio (INR) is recommended.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine.

Men subject to treatment with idarubicin must use effective contraceptive methods up to 3 months after treatment.
There are no adequate and controlled studies in pregnant women. Idarubicin should only be used during pregnancy if the potential benefits justify the potential risks to the foetus.

Breast-feeding
It is not known if idarubicin is excreted in the mother's milk. Since many drugs are, mothers must stop breast-feeding before starting treatment.

Driving and using machines
The effect of idarubicin on the ability to drive and use machines has not been systematically assessed.

3. How to use Idarubicin Injection

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dosage is normally calculated taking into account the body surface area (mg/m^2). Administration is usually intravenous.

Acute non-lymphocytic leukaemia
Adults: In acute non-lymphocytic leukaemia, the recommended dose is 12 mg/m^2 IV a day for 3 days in combination with cytarabine. Another dose pattern that can be used in acute non-lymphocytic leukaemia, as a single agent or in combination, is 8 mg/m^2 IV a day for 5 days.

Children: The recommended dose range is 10-12 mg/m^2 IV a day for 3 days in combination with cytarabine.

Acute lymphocytic leukaemia
Adults: As a single agent in acute lymphocytic leukaemia, the recommended dose is 12 mg/m^2 IV a day for 3 days.

Children: As a single agent in acute lymphocytic leukaemia, the recommended dose is 10 mg/m^2 IV a day for 3 days.

All these dosage regimens must take into account the patient's blood condition and the doses of the other cytotoxic agents when used in association.

If you are given more Idarubicin Injection than you should have received
Very high doses of idarubicin can cause acute toxicity of the heart muscle in the first 24 hours and severe suppression of blood cell production through the bone marrow within one to two weeks.
The occurrence of delayed heart failure with anthracyclines has been observed, up to several months after an overdose.

If you forgot to use Idarubicin Injection
Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects can occur very commonly: - infections; decrease in number of red blood cells, white blood cells and platelet counts in circulatory blood; marked reduction or loss of appetite; nausea, vomiting, diarrhoea, abdominal pain, burning sensation, inflammation of mucosa in the mouth; hair loss; reddish colouring of urine 1-2 days after taking the medicine: fever, headache and chills.

The following side effects can occur commonly:
- increase or decrease in heart rate, increase and irregular heart rhythm, heart function impairment; inflammation of the vein, inflammation of the vein associated with thrombosis, bleeding; haemorrhage of the gastrointestinal tract, stomach ache; increase in liver enzymes and bilirubin; skin rash, itching, hypersensitivity of irradiated skin.
The following side effects can occur uncommonly:
- general infection; secondary leukaemia; increase in blood uric acid concentration; electrocardiogram irregularities; shock; inflammation of the oesophagus, inflammation of the colon, hyperpigmentation of skin and nails, cellulitis, tissue necrosis.

The following side effects can occur rarely:
- brain haemorrhage.

The following side effects can occur very rarely:
- general severe allergic reaction; heart infection and other disorders, occlusion of a blood vessel, redness, gastric ulcers, skin reddening particularly in the limbs.

Cases of pancytopoenia, tumourallysis syndrome and local reaction have also been reported.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Idarubicin Injection

Keep this medicine out of the sight and reach of children.

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

Store in a refrigerator (2°C - 8°C). Store in the original package in order to protect from light.

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 Idarubicin Injection contains
- The active substance is idarubicin hydrochloride.
- One ml of solution contains 1 mg idarubicin hydrochloride.
- Each vial of 5 ml contains 5 mg of idarubicin hydrochloride.
- Each vial of 10 ml contains 10 mg of idarubicin hydrochloride.
- Each vial of 20 ml contains 20 mg of idarubicin hydrochloride.
- The other ingredients are: glycerol, hydrochloric acid concentrate, sodium hydroxide (for pH adjustment) and water for injection.

What Idarubicin Injection looks like and contents of the pack
Solution for injection
Clear, orange red solution, free of visible suspended particles.
Each vial of Type I colourless glass for injection contains ready to use solution of 5 mg, 10 mg or 20 mg of idarubicin hydrochloride for injection solution.
Vials of 5 ml or 10 ml or 20 ml of solution. Box of 1 vial.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Accord Healthcare Limited
Sage House
319 Pinner Road
North Harrow
Middlesex, HA1 4HF
United Kingdom

Manufacturer:

Accord Healthcare Limited

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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHPROFESSIONALS ONLY:

This medicine is intended to be administered intravenously.

Incompatibilities:
Prolonged contact with any alkaline pH solution must be avoided, since it can give rise to drug degradation. Idarubicin hydrochloride must not be mixed with heparin, as it can form a precipitate. Association with other drugs is not recommended.
Idarubicin Injection is intended to be used once only and any remaining drug must be discarded.

The ready-to-use solution of Idarubicin Injection must only be administered intravenously and given through a tube where an intravenous perfusion of 0.9% sodium chloride can flow freely for a period of 5 to 10 minutes. This method minimises the risks of thrombosis or perivenous extravasation that can lead to severe cellulitis and necrosis. Venous sclerosis can result from injection into small veins or repeated injections into the same vein.

The following recommendations for protection are given because of the toxic nature of this substance:
- The staff must be trained in the correct handling technique.
- Pregnant women must be excluded from working with this drug.
- The staff handling the drug must wear protective clothing: disposable goggles, overall, gloves and masks.
- A reconstitution area should be set up (preferably under a vertical laminar air flow). The work area should be protected with plastic-backed absorbent paper.
- All tools used for reconstitution, administration or cleaning, including gloves, must be placed at high-risk, in containers to be disposed of at high-temperatures in incinerators.

Spillages or leaks must be treated with diluted (1% chlorine) sodium hypochlorite and then with water. All cleaning material must subsequently be treated as described above.

Accidental contact with skin and eyes must be treated immediately by washing thoroughly with water, or soap and water, or sodium bicarbonate solution; medical attention may be necessary. Dispose of any unused solution.