PATIENT INFORMATION LEAFLET

Amsidine 75 mg/1.5 ml Concentrate and Solvent for Concentrate for Solution for Infusion

Amsacrine Concentrate and Solvent for Concentrate for Solution for Infusion

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING THIS MEDICINE.

Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist.
If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT AMSIDINE IS AND WHAT IT IS USED FOR

Amsidine is one of a group of medicines called antineoplastic (anticancer) agents.

It is used to treat acute leukaemia, a form of cancer of the white cells in your blood.

2. BEFORE YOU RECEIVE AMSIDINE

You should not be given Amsidine if:
• You know that you are allergic to amsacrine or to any of the other ingredients (see section 6 of this leaflet)
• You are already receiving other treatments for cancer, including radiation, which have affected your bone marrow or you have received treatments in the past (your doctor will advise you)
• You are under 12 years old.
• You are breast feeding

Speak to your doctor *before* you are given this injection if any of these apply to you.

Before you are given Amsidine, your doctor will take special care if any of the following situations apply to you. Make sure your doctor is aware of these situations if it is not already obvious:

• You have ever had a kidney or liver disease
• You have any problem with your heart
• You have a problem with your nervous system or brain
• You have been told that the potassium level in your blood is too low
• You have pre-existing bone marrow depression
• You have a raised uric acid level.

Speak to your doctor before you are given this injection if any of these apply to you.

Taking or receiving other medicines:
Tell your doctor before you are given this medicine if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines can interact with Amsidine which can significantly alter their effects. These drugs include:
• Vaccines such as Common Influenza and Pneumonia Vaccine.
• Other medicines or radiation used in the treatment of cancer.

There is a potential for interaction with other protein binding drugs.

If you are already taking one of these medicines, speak to you doctor before you receive Amsidine.

Pregnancy and breast-feeding
Men as well as women should use effective contraception.

Tell your doctor before you are given this medicine if you are or think you may be pregnant or are planning to become pregnant, or are breast-feeding.

Do not use this medicine in the first 3 months of pregnancy.

This medicine should not be given during pregnancy especially during the first three months of pregnancy. You must speak to your doctor about the possible effects this medicine might have on your baby *before* you are given this medicine.
You should not take this medicine if you are breast-feeding. You should avoid becoming pregnant for at least three months after your treatment with Amsidine has stopped.

Men
Amsidine affects sperm. You should avoid fathering a child for at least six months after your treatment has stopped.

Driving and using machines
Amsidine should not affect your ability to drive or use machinery. However, if you experience any side effects after having the injection ask your doctor's advice if you can drive.

3. HOW AMSIDINE IS GIVEN

You will be in hospital when you are given Amsidine.

The concentrate must be diluted with the enclosed diluent. The diluted solution is then added to a sugar solution and slowly injected into a vein over 60 - 90 minutes. This is known as an infusion and will be performed under the supervision of a doctor experienced in cancer treatment.

The dose will be calculated by your doctor according to your age and the surface area of your body (normally 90mg per square metre).

You will be given one infusion a day for 5 - 8 days.

Blood monitoring should be done for all patients treated with Amsidine. Close monitoring of the blood levels should be done including the complete blood counts,
urine tests and in some cases blood Amsidine monitoring along with liver and kidney function tests to detect any problems.

Following this initial dosing period, further doses will be given every 3 – 4 weeks, depending on the number of your blood cells. This second course of treatment will generally be one third of the original dose and will either be given all on one day or divided up over 3 days.

If Amsidine decreases the number of your blood cells too much, it may be necessary for your doctor to give you a blood transfusion.

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

If you think you have been given more Amsidine than you should have
As the injection will be administered under the supervision of a doctor, it is unlikely that you will be given more than is necessary. However, if you have any concerns about the dose of your medicine discuss them with your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines Amsidine can sometimes cause side-effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Amsidine can make you more likely to catch infections. If you think you have an infection, a sore throat, fever, chills, or achiness during treatment you should tell your doctor immediately.
The side-effects reported with Amsidine are as follows:

Tell your doctor straight away if you notice any of the following side effects:

Very Common – (affects more than 1 in 10 people)
• Feeling sick (nausea) or vomiting
• Diarrhoea
• Abdominal pain
• Ulcers in the mouth
• On investigation, if there is an increase in liver enzymes
• Inflammation of the veins at the site of the injection

Common – (Affects more than 1 in 10 people)
• Increase or decrease in blood cell count on investigation
• Increased risk of bruising or bleeding.
• Reduced potassium levels in the blood
• Emotional instability
• Epilepsy (Fits)
• Heart Problems (racing heart, heart failure)
• Breathlessness
• Yellowing of the skin or whites of the eyes caused by liver or blood problems
• Hair Loss
• Skin rash
• Raised itchy red welts on the surface of the skin
• Blood in the urine
• Fever
• Skin Irritation, black discolouration and redness and swelling at the injection site
• Purpura
• Infection

Rare – (affects less than 1 in 1,000 people)

• Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
• Increase or decrease in weight
• Confusion
• Headache, dizziness
• Reduced sense of touch
• On urine examination, high levels of proteins may be seen
• On blood examination, high levels of some enzymes may be seen
• Granulocytopenia, leukopenia
• Not creating urine (of the kidney) (anuria)
• Sudden insufficiënt kidneyfunction (kidney insufficiency)

Not Known – (cannot be estimated from the available data)
• Bone marrow failure
• Cardiac arrest

Painful swelling of the joints (Gout) may be seen in some cases due to increase in uric acid levels in the blood.

If you develop sign of serious allergic reaction, you must contact you doctor immediately.

If you get any of these side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor at once.

Certain other unwanted effects can only be detected by your doctor, these include blood disorders, and changes in liver and kidney function

Although the above list of possible side effects appears daunting, acute leukaemia is a serious disease which requires aggressive treatment.

5. HOW TO STORE AMSIDINE

The storage of Amsidine will not be your responsibility.

However, keep in a dry place and do not store above 25°C. Keep in the outer carton in order to protect from light.

Keep out of the reach and sight of children.

Do not use Amsidine after the expiry date which is stated on the vial and outer carton.
If only part used, discard the remaining solution.

6. FURTHER INFORMATION

What Amsidine contains
The active substance is amsacrine.
The other ingredients are N,N, Dimethylacetamide, L-lactic acid and water for injection.

What Amsidine looks like and contents of pack
Amsidine comes as two types of small glass bottles. One small sealed clear glass bottle (vial) contains the active ingredient, which is 75mg of amsacrine.

It also contains an inactive ingredient, which is N,N, dimethylacetamide in 1.5ml as a clear bright orange/red liquid.

A second glass bottle (vial) contains 13.5ml of a solution of L-lactic acid in Water for Injection.

Marketing Authorisation Holder and Manufacturer
Eurocept International BV
Trapgans 5
1244 RL Ankeveen
The Netherlands

Amsidine is a trade mark.

This leaflet was last approved in October 2018.