

ASADIN INJECTION

Arsenic Trioxide (1mg/ml)

What is in this leaflet

1. What *ASADIN Injection* is used for
2. How *ASADIN Injection* works
3. Before you use *ASADIN Injection*
4. How to use *ASADIN Injection*
5. While you are using it
6. Side effects
7. Storage and Disposal of *ASADIN Injection*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *ASADIN Injection* is used for

ASADIN Injection is used for treating a type of leukemia (cancer of the blood cells) called acute promyelocytic leukemia (APL).

How *ASADIN Injection* works

Arsenic Trioxide causes cell death in promyelocytic leukemia cells. Arsenic Trioxide also causes damage to the abnormal protein which causes leukemia.

Before you use *ASADIN Injection*

-When you must not use it

You should not receive this medicine if you have had an allergic reaction to arsenic, or if you are pregnant.

Pregnancy and lactation

Do not take *ASADIN Injection* if you are pregnant, trying to get pregnant or think you may be pregnant. Using this medicine while you are pregnant can harm your unborn baby. Use an effective form of birth control to keep from getting pregnant. If you have become pregnant while using the medicine, tell your doctor right away.

ASADIN Injection is found in breast milk. Do not take *ASADIN Injection* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Medicines used to treat cancer can have many side effects. Please inform your doctor if you have

- Fever, difficulty breathing or unexplained weight gain

- Electrolyte imbalance

Your doctor will perform regular blood and ECG test for you. Please ask your doctor and understand all the risks and benefits before receiving this medicine. It is important for you to work closely with your doctor during your treatment.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use *ASADIN Injection*

- How much to use

Your doctor will prescribe your exact dose and tell you how often it should be given. This medicine is given through a needle placed in one of your veins. The medicine is usually given slowly, so the needle will remain in place for 2-4 hours. In some cases, it may take up to 4 hours for each dose of this medicine to be given.

- When to use it

You will receive this medicine while you are in a hospital or cancer treatment center. A nurse or other trained health professional will give you. It may also be given by a home health caregiver, if prescribed by your doctor.

- How long to use it

Continue taking *ASADIN Injection* for as long as your doctor recommends.

- If you forget to use it

This medicine is to be given on a fixed schedule. If you miss a dose, call your doctor, home health caregiver, or treatment clinic for further instructions.

- If you use too much (overdose)

If too much dosage is taken by accident, call your doctor or poison control center, or go to the nearest emergency room.

Get emergency help immediately if any of the following symptoms of overdose occur:

- Confusion
- Convulsions (Seizures)
- Muscle weakness

While you are using it

- Things you must do

Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products. Make sure your doctor knows if you are also using:

- Diuretics (water pills)
- Amphotericin B
- Medicine for heart rhythm problems (such as thioridazine).

Make sure your doctor knows if you have kidney disease, heart disease, or a history of heart rhythm problems.

Your doctor will need to check your progress at regular visits while you are using this medicine. Be sure to keep all appointments.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *ASADIN Injection* to anyone else, even if they have the same symptoms or condition as you.

Side effects

Call your doctor right away if you have any of these side effects:

- Allergic reaction: Itching or hives, swelling in face or hands, swelling or tingling in the mouth or throat, tightness in chest, trouble breathing
- Fever
- Irregular heartbeat
- Unusual bleeding or bruising

If you have problems with these less serious side effects, talk with your doctor.

- Cough
- Headache
- Muscle, joint, or bone pain
- Nausea, vomiting
- Skin dryness or itching
- Stomach pain
- Tiredness

- Ingredients

- Active ingredient:
Arsenic Trioxide 1mg/ml

- Inactive ingredients:
Acetic Acid, Edetate Disodium,
Sodium Hydroxide

- MAL number

MAL20071712AZ

Manufacturer

TTY Biopharm Company Limited
838, Chung Hwa Rd., Sec. 1,
Chungli Dist., Taoyuan City,
32069, Taiwan.

Product Registration Holder

Pharm-D Sdn. Bhd. (535448-K)
8B, Jalan 1/137C,
Bedford Business Park,
Off Jalan Kelang Lama,
58000 Kuala Lumpur, Malaysia.

Date of revision

24/2/2017

Serial Number:

BPFK(R4/1)240217/00004

PLEASE TELL YOUR DOCTOR IF YOU HAVE ANY OTHER SIDE EFFECTS THAT YOU THINK ARE CAUSED BY THIS MEDICINE.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of ASADIN Injection

- Storage

Do not use after expiration date printed on the label. Please store below 30°C and protected from light. Please keep out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

ASADIN Injection is formulated as a clear and colorless injectable solution of Arsenic Trioxide. Each mL contains 1mg of Arsenic Trioxide.