

Indomethacin IV Mylan

Indomethacin sodium trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Indomethacin IV Mylan. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of Indomethacin IV Mylan against the benefits they expect it will have for your baby.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Indomethacin IV Mylan is used for

Indomethacin IV Mylan is used in premature babies to close the patent ductus arteriosus.

While a baby is inside its mother's womb it does not need to use its lungs. An unborn baby has a blood vessel called a 'ductus arteriosus' near the heart which allows the baby's blood to bypass its lungs and circulate to the rest of its body.

When the baby is born and starts using its lungs the ductus arteriosus normally closes up.

However, in some cases this does not happen. This can cause heart problems in the baby.

The doctor has prescribed Indomethacin IV Mylan for your baby because your baby has a ductus arteriosus which has not closed properly. Indomethacin IV

Mylan can help close this blood vessel.

If the ductus arteriosus remains open, blood intended for the body may be returned to the lungs, overloading the lung's blood vessels, making the lungs and heart work harder to pump blood to the rest of the body. This can lead to failure to gain weight, shortness of breath, a fast heart rate, frequent chest infections, and sometimes heart failure.

In premature infants the extra blood flow to the lungs may interfere with the functioning of the heart and, even more significantly, with that of the lungs which are immature. In these cases, fluid restriction, Indomethacin IV Mylan, or surgery may be used to close the ductus.

Indomethacin IV Mylan belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

It is not known exactly how Indomethacin IV Mylan works, but it is believed that it stops the production of prostaglandin.

Prostaglandin is a naturally occurring chemical in the body which keeps the ductus arteriosus open.

Indomethacin IV Mylan is not addictive.

Before your baby receives Indomethacin IV Mylan

When your baby must not be given it

Indomethacin IV Mylan should not be given to your baby if:

- **your baby has proven or suspected infection that is not being treated**
- **your baby has bleeding, especially in the brain or stomach**
- **your baby has a low blood platelet count**
- **your baby has blood clotting problems**
- **your baby has or is suspected of having an intestinal problem, called necrotising enterocolitis**
- **your baby has significantly impaired kidney function.**
- **your baby has heart disease at birth and it is necessary for them to have a patent ductus arteriosus for satisfactory blood flow in the lungs and throughout the body.**
- **your baby has a peptic ulcer (ie stomach or duodenal ulcer), a recent history of one, or has had peptic ulcers before**

Indomethacin IV Mylan should not be given if:

- **the packaging is torn or shows signs of tampering**
- **the expiry date (EXP) printed on the pack has passed.**
If the medicine is given after the expiry date has passed, it may not work.

Your baby's doctor will be aware of these, but if you are worried or confused, talk to the doctor treating your baby.

Before your baby is given it

There are other things regarding Indomethacin IV Mylan which the baby's doctor should know about. These include, if:

1. your baby has any allergies to:

- any other medicines including aspirin or other NSAID medicines
- any other substances, such as foods, preservatives or dyes

2. your baby has or has had any medical conditions, especially the following:

- kidney or liver disease
- heart disease
- heart failure
- high blood pressure
- build-up of fluid

3. your baby currently has an infection

If Indomethacin IV Mylan is used while your baby has an infection, it may hide some of the signs of an infection. This may make you think, mistakenly, that your baby is better or that the infection is less serious than it might be.

These are things that your baby's doctor will look out for.

Taking other medicines

There are certain medicines, which if given together with Indomethacin IV Mylan, may cause unwanted effects. These include:

- aspirin, salicylates or other NSAID medicines
- digoxin, a medicine used to treat heart failure
- diuretics, also called fluid or water tablets
- certain blood pressure medicines
- gentamicin or amikacin, antibiotics used to treat infection

These medicines may be affected by Indomethacin IV Mylan, or may affect how well it works. Your baby may need to take different amounts of medicine, or may need to take different medicines.

Your baby's doctor will be aware of the effects Indomethacin IV Mylan and these medicines can have on each other, but if you are worried or confused, you should talk to the doctor.

How Indomethacin IV Mylan is given

Babies with patent ductus arteriosus are cared for in a special newborn intensive care unit where the baby's condition is closely monitored.

Your baby will be given Indomethacin IV Mylan injection by a doctor or nurse, who will know how to make up the injection. They will do this by adding sterile water or saline (salt and water) to the vial.

The doctor will decide what dose and how long your baby will receive Indomethacin IV Mylan. This depends on their condition and other factors, such as their age and weight.

Side effects

Tell the doctor or nurse as soon as possible if your baby appears unwell while receiving Indomethacin IV Mylan

Indomethacin IV Mylan helps most babies with patent ductus arteriosus but it may have unwanted side effects in a few babies.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Your baby may need medical treatment if they get some of the side effects.

Ask the doctor or, nurse to answer any questions you may have.

Tell the doctor or nurse if your baby has any of the following and they worry:

- oozing from the skin after needle puncture

Tell the doctor or nurse immediately if your baby has any of the following:

- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- vomiting blood or material that looks like coffee grounds
- any other unusual bleeding or bruising
- vomiting, stomach bloating, diarrhoea
- fluid retention, weight gain
- passing less urine than is normal

These are serious side effects. Your baby may need urgent medical attention.

Other side effects have been reported in adults taking indomethacin for the treatment of different types of arthritis and shoulder pain, and may occur in babies given Indomethacin IV Mylan These include:

- constipation
- signs of liver problems, including, yellowing of the skin and eyes, stomach swelling, and dark coloured urine
- convulsions, coma
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.

Other side effects not listed above may also occur in some patients. Tell the baby's doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. Your baby may not experience any of them.

Storage

Indomethacin IV Mylan will be stored in the hospital pharmacy or on the ward.

It is kept in a cool dry place where it is protected from light and where the temperature stays below 25°C.

Product description

What it looks like

Indomethacin IV Mylan comes as a white to yellow lyophilised powder or plug in a single dose vial. It is made up into a solution for injection before being given to your baby.

Ingredients

Active ingredient:

- Indomethacin sodium trihydrate, equivalent to indomethacin 1 mg per vial

Supplier

Indomethacin IV Mylan is supplied in Australia by:

Alphapharm Pty Limited
(ABN 93 002 359 739)
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.alphapharm.com.au

Australian Register Number:
AUST R 208055.

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Mylan _cmi\Nov15/00**

**This leaflet was prepared on 11
November 2015**