

INDOCID® P.D.A.

Indomethacin sodium trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about INDOCID P.D.A. 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 INDOCID P.D.A. 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 with the medicine. You may need to read it again.

What INDOCID P.D.A is used for

INDOCID P.D.A. is used in premature babies, usually weighing between 500 to 1750g, to close the patent ductus arteriosus, when after 48 hours of usual medical management has not been effective.

Patent ductus arteriosus is a heart defect in which the channel between the two large blood vessels from the heart fails to close after birth. If the channel (ductus arteriosus) remains open, the lungs and heart have to work harder to pump blood to the rest of the body. This can lead to failure to gain weight, shortness of breath, frequent chest infections, and sometimes heart failure.

INDOCID P.D.A. belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

INDOCID P.D.A. is not addictive.

Before you receive INDOCID P.D.A.

When your baby must not be given it

Do not give INDOCID P.D.A. 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

Do not give INDOCID P.D.A. 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.

If you are not sure whether your baby should be given INDOCID P.D.A., talk to your doctor.

Before your baby is given it

Tell your doctor 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 INDOCID P.D.A. 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.

If you have not told your doctor about any of the above, tell them before your baby is given any INDOCID P.D.A.

Taking other medicines

Tell your doctor if your baby is receiving any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and INDOCID P.D.A. may interfere with each other. These include:

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

These medicines may be affected by INDOCID P.D.A., 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 doctor will advise you.

Your doctor and pharmacist has more information on medicines to be careful with or avoid while being given INDOCID P.D.A.

How INDOCID P.D.A. is given

INDOCID P.D.A. is given as an injection into a vein.

INDOCID P.D.A. must only be given by a doctor or nurse.

Your doctor will decide what dose and how long your baby will receive INDOCID P.D.A. This depends on their condition and other factors, such as their age and weight.

Side Effects

Tell your doctor, nurse or pharmacist as soon as possible if your baby appears unwell while receiving INDOCID P.D.A.

INDOCID P.D.A. 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 your doctor, nurse or pharmacist to answer any questions you may have.

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

- oozing from the skin after needle puncture

Tell your 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 INDOCID P.D.A. 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 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

INDOCID P.D.A. will be stored in the 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

INDOCID P.D.A. comes as a white to yellow powder in a single dose vial.

Ingredients

Active ingredient:

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

Supplier

INDOCID P.D.A. is supplied in Australia by:

Pharmalink Pty Ltd
Level 8, 67 Albert Avenue,
Chatswood NSW 2067
Australia

This leaflet was prepared in December 2006.

Australian Register Number:
AUST R 10482