PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PEDEA, 5 mg/mL solution for injection

Ibuprofen

Sugar free

Read this leaflet carefully before PEDEA is administered to your baby

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What PEDEA is and what is used for

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 the *ductus arteriosus* near the heart which allows the baby's blood to bypass the lungs and circulate to the rest of the body.

When the baby is born and starts using its lungs the *ductus arteriosus* normally closes. However, in some cases this does not happen. The medical term for this condition is 'patent *ductus arteriosus*,' i.e. an open *ductus arteriosus*. This can cause heart problems in your baby. This condition is much more frequent in premature newborn than in full-term newborn infants.

PEDEA, when given to your baby, can help to close the *ductus arteriosus*.

2. What you need to know before PEDEA is administered to your baby

PEDEA should not be administered to your baby:

- if they are hypersensitive (allergic) to ibuprofen or to any of the other ingredients of PEDEA (listed in section 6)
- if they have a life-threatening infection which has not been treated
- if they are bleeding, especially if the bleeding is inside the skull or in the intestines
- if they have decreased blood cells called platelets (thrombocytopenia) or other problems with their blood clotting
- if they have kidney problems
- if they have other problems with their heart which require the *ductus arteriosus* to remain open so that adequate circulation of the blood is maintained
- if they have certain problems with their intestines (a condition called necrotising enterocolitis)

Warnings and precautions

Before PEDEA is given to your baby, your baby's heart will be examined to confirm that the *ductus arteriosus* is open.

PEDEA should not be given in the first 6 hours of life.

PEDEA should not be used prophylactically.

PEDEA may cause problems with your baby's respiratory system. If the blood oxygen levels of your baby decreases after receiving PEDEA, the healthcare professional will monitor the blood pressure in your baby's lungs.

PEDEA should not be used if your baby is suspected of having liver disease, signs and symptoms of which include yellowing of the skin and eyes.

PEDEA may reduce the ability of your baby's blood to clot. Your baby should therefore be watched for signs of prolonged bleeding. Your baby may develop some bleeding from the intestines and the kidneys. To detect this, your baby's stools and urine may be tested to determine if there is any blood present in them. If your baby develops intestinal bleeding or stomach ulcers, your baby's doctor will stop the treatment with PEDEA.

PEDEA may increase the adverse effects of antibiotics known as aminoglycosides. If your baby has to receive aminoglycosides together with PEDEA your baby's doctor or healthcare professional will strictly monitor their condition.

Serious skin reactions have been reported in association with PEDEA treatment. The treatment with PEDEA should be stopped, and seek medical attention immediately, if your baby develops any skin rash, lesions of the mucous membranes (e.g., in the mouth and/or nose), blisters or any other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

PEDEA may reduce the amount of urine your baby passes. If this is significant, your baby's treatment may be stopped until the volume of urine returns to normal.

If your baby is already suffering from an infection that is being treated, the doctor will treat your baby with PEDEA only after careful consideration of your baby's condition.

PEDEA should be carefully administered to your baby by the healthcare professional, to avoid damage to the skin and surrounding tissues.

PEDEA may be less effective in very premature babies less than 27 weeks of gestational age.

Other medicines and PEDEA

Always tell your healthcare provider if your baby is taking any other medicine. (This includes all

complementary or traditional medicines.)

Due to effects on the kidneys, PEDEA may lead to reduced excretion of some medicines.

Certain medicines, if given together with PEDEA, may cause side effects. Your doctor will consider the medicines that may interact with PEDEA. Some of these are detailed below:

- Your baby may have problems passing urine and may have been prescribed diuretics. PEDEA may reduce the effect of these medicines. Diuretics can increase the risk of kidney toxicity caused by PEDEA.
- Your baby may be given medicines to reduce the blood pressure, e.g. ACE inhibitors, beta blockers and diuretics. The blood pressure lowering effects of these medicines may be reduced by PEDEA.
- Your baby may be given anticoagulants (medicines preventing blood clotting). PEDEA may increase the anti-clotting effect of this product.
- Your baby may be given corticosteroids to prevent inflammation. PEDEA may increase the risk of bleeding in the stomach and intestines.
- Your baby may be given nitric oxide to improve blood oxygenation. PEDEA may increase the risk of bleeding.
- If your baby is using zidovudine, blood counts one to two weeks after starting use together with PEDEA are recommended.
- Ritonavir may increase the plasma concentrations of PEDEA.
- Your baby may be given aminoglycosides (one family of antibiotics) to treat infection. PEDEA may increase blood concentrations of aminoglycosides and thus increase the risk of toxicity on the kidneys and ears.

PEDEA contains sodium

PEDEA contains less than 1 mmol sodium (15 mg) per 2 mL, which means that PEDEA is essentially "sodium-free".

3. How PEDEA is given

PEDEA will only be given to your baby in a special neonatal intensive care unit by qualified healthcare

professionals.

A course of therapy is defined as three intravenous injections of PEDEA given at 24 hour intervals. The first injection should be given after the first 6 hours of life. The dose to be administered will be calculated from the weight of your baby. It is 10 mg/kg for the first administration and 5 mg/kg for the second and the third administrations.

The calculated amount will be given by infusion in a vein over a period of 15 minutes.

If 48 hours after this first course of treatment, the *ductus arteriosus* is not closed, or it reopens, your baby's doctor may decide to give a second course of treatment.

If the condition is unchanged after the second course of therapy, surgery may be necessary.

If your baby receive more PEDEA than they should

Since a healthcare provider will administer PEDEA, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

PEDEA may cause side effects.

Not all side effects reported for PEDEA are included in this leaflet. Should the general health of your baby worsen of if your baby experience any untoward effects while receiving PEDEA, please consult your baby's healthcare provider for advice.

The following side effects have been reported with PEDEA:

Frequent side effects:

- decrease in the number of platelets in the blood (thrombocytopenia)
- decrease in white blood cells called neutrophils (neutropenia)
- increase in creatinine level in the blood
- decrease in sodium level in the blood
- breathing problems (bronchopulmonary dysplasia)
- bleeding inside the skull (intraventricular haemorrhage) and brain injury (periventricular leukomalacia)

- bleeding in the lungs (pulmonary haemorrhage)
- perforation or bleeding of the intestine which could be fatal, injury of the intestinal tissue (necrotising enterocolitis), stomach ulcers, nausea, vomiting, diarrhoea, wind (flatulence), constipation, indigestion (dyspepsia), abdominal pain, tarry black stools due to intestinal bleeding (melena), vomiting blood (hematemesis), sore in the mouth (ulcerative stomatitis), exacerbation of inflammation of the bowel (colitis and Crohn's disease), inflammation of the stomach (gastritis)
- reduced volume of urine passed (oliguria), blood in urine (haematuria), fluid retention
- increase in blood pressure in the lungs

Less frequent side effects:

- acute failure of the kidney's functions
- below normal oxygen content in arterial blood (hypoxaemia)

Frequency unknown:

- high blood pressure (hypertension), heart failure
- perforation of the stomach
- a red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, upper extremities, and mucous membranes accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis, Stevens-Johnson syndrome, toxic epidermal necrolysis); treatment with PEDEA should be stopped if your baby develops these symptoms, seek medical attention immediately (see also section 2)

If you notice any side effects not mentioned in this leaflet, please inform your baby's doctor or your pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PEDEA.

5. How to store PEDEA

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use after the expiry date stated on the label or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PEDEA contains

- The active substance is ibuprofen. Each mL of solution contains 5 mg ibuprofen. Each 2 mL ampoule contains 10 mg ibuprofen.
- The other ingredients are trometamol, sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), and water for injections.

What PEDEA looks like and contents of the pack

PEDEA is a clear colourless to slightly yellow solution, free from visible particles.

It is filled into colourless, clear 2 mL Type I glass ampoules.

PEDEA is supplied in packs of 4 x 2 mL ampoules.

Holder of Certificate of Registration

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