

ALGOPEDOL® – Sucrose 24% oral solution for Paediatric Use

WHAT IS ALGOPEDOL®?

ALGOPEDOL® is a preservative-free, oral solution of sucrose 24% for pediatric use, and should not be used for injection. As a single-dose dispenser, **ALGOPEDOL®** allows a safe administration, and simplifies clinician workflow by allowing the administration of sucrose directly onto the tip of an infant's tongue or buccal surface.

COMPOSITION AND PACKS SIZES

Sucrose, Distilled Water.

- 2ml single-dose vial of sucrose 24%.
- Packs of 5 vials
- Packs of 100 vials
- For Single Use

INDICATIONS FOR USE OF ALGOPEDOL®

Pain is often a traumatic experience for preterm and term infants. Repeated episode of pain, even minor will induce stress and anxiety, which will increase this unpleasant feeling in preterm and term infants.

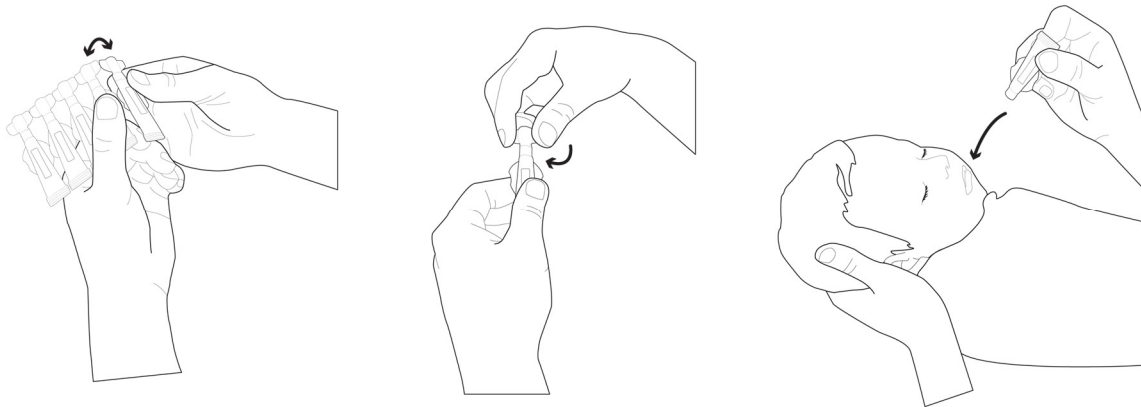
In conjunction with non-nutritive sucking, **ALGOPEDOL®** allows non-Pharmacological management of procedural pain in preterm and term infants. Many clinical studies demonstrated efficacy of sucrose 24% oral solution for management of procedural pain, and its use is even recommended by some Health Authorities.

In conjunction with non-nutritive sucking, **ALGOPEDOL®** helps to calm and soothe preterm and term infants during painful procedures like:

- Arterial or venous blood draw,
- Blood sugar level test,
- immunization,
- Adhesive tape removal,
- Dressing change, weight check,
- X-Ray providing discomfort.

ALGOPEDOL® can be used before a blood sugar level test, as infants would not be administered large enough volumes to effect blood glucose levels, and the period between blood sampling and administration of **ALGOPEDOL®** would be too small.

HOW TO USE ALGOPEDOL®



Detach a vial and remove the flat upper tab section by twisting.

Introduce the tip of the dispenser bottle into the side of infant's mouth onto anterior portion of the tongue and dispense solution slowly, then offer pacifier.

Wait 2 minutes and then perform intervention.

ALGOPEDOL® can be administered up to 4 times per 24 hours in preterm infants and up to 6-8 times per 24 hours in full term infants.

If needed, the vial can be closed, and be used again in the same infant within a period of 8 hours.

Do not make use of an opened vial after 8 hours. DO NOT use the same vial for more than one infant.

RECOMMENDED DOSAGE

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| Preterm infant less than 1,5 kg | 0,20 ml |
| Preterm infant from 1,5 to 2 kg | 0,30 ml |
| Preterm infant from 2 to 2,5 kg | 0,50 ml |
| Preterm infant from 2,5 to 3 kg | 1 ml |
| Infant from 3 kg (less to 4 months of age) | 2 ml |

BEFORE YOU TAKE ALGOPEDOL®?

ALGOPEDOL should be administered with caution in Preterm and term infants with swallowing problems, Cardio-respiratory instability or any major digestive pathology requiring to keep an empty stomach.

ALGOPEDOL® oral solution should always be administered under the supervision of an adult.

CONTRAINDICATIONS:

- Infants with esophageal atresia ;
- Infants with tracheal esophageal fistula ;

- Confirmed or suspected gastrointestinal pathology at high risk for necrotizing Enterocolitis (NEC) ;
- Infants unable to swallow,
- Infants with known fructose intolerance.

Oral Solution for pediatric use, DO NOT INJECT.

STORAGE CONDITIONS

Store at room temperature. Do not use **ALGOPEDOL**[®] after the expiry date which is stated on the carton, and the vial.

FURTHER INFORMATION

MEDICAL DEVICE CLASS I



MANUFACTURER :

EPMC Pharma France
67, rue du Luxembourg
F-59777 Lille (France)

DISTRIBUTOR :

This leaflet was created or last approved on : Septembre 2012