PACKAGE INSERT

Ipradol ampoules

Manufacturer
HAFSLUND NYCOMED PHARMA AG, Linz

Composition
Each ampoule of 2 ml contains 5 µg hexoprenaline sulfate, 0.0400 mg sodium pyrosulphite (equivalent to 0.027 mg SO_2) in blood-isotonic sodium-chloride solution.

Properties and efficacy
IPRADOL is a sympathomimetic with a nearly selective action on β_2-adrenergenic receptors and shows a strong, long-lasting bronchodilating effect while developing only a weak stimulating effect on β_1-receptors (rise of heart rate).

Indications
Imminent or acute attack of bronchial asthma, bronchitis (especially with spastic component), chronic bronchitis due to pulmonary emphysema, bronchial spasms of various origins.

Mode of application
i.v. injection or i.v. infusion

OPC ampoules
Requires no filing
Instructions for the use of OPC (one-point-cut) ampoules:

Point tip with coloured dot up!
Allow solution in the tip to run down by gently thumbing and shaking the ampoule.

Point tip with coloured dot up!
Break off tip as shown in the figure.

Dosage
For maximum therapeutic effect, determine individually most effective dose.

Adults:
For acute asthma attacks, inject 1 ampoule, in cases of severe dyspnoea inject 1½ to a maximum of 2 ampoules. In cases of status asthmaticus, administer 1 ampoule 3 to 4 times over a period of 24 hours.

Children:	1 — 3 times daily
3 — 6 months	1 µg
6 — 12 months	2 µg
1 — 3 years	2 — 3 µg
3 — 10 years	3 — 4 µg

The ampoule should be injected slowly i.v. (2 minutes per ampoule). It is possible to dilute the ampoule with blood-isotonic sodium chloride or glucose solution.

Contra-indications
Hypersensitivity to one of the components of IPRADOL. Due to the sulphite contents, IPRADOL ampoules must not be administered to asthma patients suffering from hypersensitivity to sulphite.
Hyperthyroidism, heart diseases, especially tachycardiac irregularities, myocarditis, mitral valve defects and idiopathic hypertrophic subvalvular aortic stenosis, severe liver or kidney disease, narrow-angle glaucoma.
In cases of permanent hypertension and recent myocardial infarction, special caution has to be taken when administering IPRADOL.
Pregnancy and lactation:
During pregnancy, IPRADOL should be administered only after a detailed risk/benefit evaluation, especially during the first trimenon and, due to its tocolytic effect, immediately before or during parturition.
No data are available on the use of IPRADOL during lactation.

Side effects
IPRADOL is generally well tolerated.
During treatment, restlessness, dizziness, tremor, sweating, palpitation and increase in pulse rate may occur. In rare cases, sickness, nausea or vomiting may occur.
Drug contains sulphite. Certain individuals, especially asthma patients, may show hypersensitive reactions to this component marked by: nausea, diarrhea, laboured breathing, acute asthma attack, disturbances of consciousness or shock. These reactions develop differently in every individual and may lead to life-threatening situations.

Interactions
Non-selective β-receptor blockers decrease or completely neutralize IPRADOL's action.
Methylxanthines like theophylline intensify IPRADOL's effect.
The increased storage of glycogen in the liver under glucocorticoids is decreased due to IPRADOL's glycogenolytic action.
The hypoglycaemic effect of oral antidiabetics is decreased by IPRADOL.
The simultaneous use of other sympathomimetic drugs, e.g. certain circulatory and asthma medications, is not recommended since it might lead to increased effects on the heart and to symptoms of overdose.
IPRADOL must not be administered during pregnancy in combination with drugs containing calcium or vitamin D, as well as dihydrotachysterol or mineral corticoids.
A sensitization of the heart to sympathomimetics through administration of certain narcotics (e.g. halothane) is possible. Simultaneous administration may cause cardiac irregularities.

Compatibility
Sulphite is a highly reactive compound. Therefore IPRADOL should not be mixed with other drugs, except with blood-isotonic sodium chloride and glucose solution.

Special warnings
When administering IPRADOL to diabetics, frequently check blood-sugar levels.
Note the expiry date!

Package sizes
5 x 2 ml, 5 x 5 x 2 ml (multi-pack)

Shelf life
60 months

Storage
Protect from light!

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