Bundesamt für Sicherheit
im Gesundheitswesen

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Ihr Zeichen:

Betreff: *Indium* – hältige Arzneispezialitäten – Änderungen der Fach- und Gebrauchsinformationen aufgrund des HBD – PSUR Worksharing Projektes

Sehr geehrte Damen und Herren,

basierend auf der Evaluierung des PSURs im EU-HBD-worksharing Projekt (Verfahrensnummer: HU/H/PSUR/0013/001) kommt es zu der Empfehlung, folgende Ergänzungen in die **Fach- und Gebrauchsinformation** aller Indium– hältigen Arzneispezialitäten aufzunehmen.

Sollten diese bereits aufgenommen worden sein, betrachten Sie dieses Schreiben als gegenstandslos.

Fachinformation

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients or to any of the components of the labeled radiopharmaceutical.

Information on contraindications to particular indium[^{111}In]-labelled pharmaceuticals prepared by radiolabelling with indium[^{111}In] chloride will be supplied by the manufacturer of the pharmaceutical to be radiolabelled.

4.4 Special warnings and precautions for use

The contents of the vial of Indium [^{111}In] Chloride Solution are not to be administered directly to the patient without first undergoing the preparative procedure.

Information concerning special warnings and precautions for use of indium[^{111}In]-labelled pharmaceuticals prepared by radiolabelling with indium[^{111}In] chloride will be supplied by the manufacturer of the pharmaceutical to be radiolabelled.

<u>Individual benefit/risk justification</u>

For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Paediatric population

Paediatric population, see section 4.2.

General warnings:

Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisation.

Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

Specific warnings

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

4.5 Interactions with other medicinal products and other forms of interaction

Information concerning interactions associated with the use of indium[^{111}In]-labelled pharmaceuticals prepared by radiolabelling with indium[^{111}In] chloride will be supplied by the manufacturer of the pharmaceutical to be radiolabelled.

4.6 Fertility, pregnancy and lactation

There is some evidence from animal experiments of teratogenicity of indium in very high doses compared with the maximal possible concentration of free indium chloride in a labeled pharmaceutical.

The availability of data on the use of indium [^{111}In]-labelled pharmaceuticals, prepared by radiolabelling with indium [^{111}In] chloride, in pregnancy and lactation will be specified by the manufacturer of the pharmaceutical to be radiolabelled.

Women of childbearing potential

When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques not using ionising radiation should be offered to the patient.

Pregnancy

Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Only imperative investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and foetus.

The absorbed dose to the uterus following administration of indium [^{111}In]-labelled pharmaceuticals prepared by radiolabelling with indium [^{111}In] chloride will be dependent on the specific pharmaceutical being radiolabelled and information will be available from the manufacturer of the pharmaceutical to be labelled. Doses above 0.5mGy should be regarded as a potential risk for the foetus. Advice on avoidance of pregnancy until the calculated dose to the uterus is below 0.5mGy should be given to women of child-bearing potential.

Breastfeeding

Before administering radiopharmaceuticals to a mother who is breastfeeding consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breastfeeding, and to what is the

most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity in breast milk. Breast feeding can be restarted when the level in the milk will not result in a radiation dose to the child greater than 1 mSv.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Possible side-effects following the intravenous administration of an indium-111-labelled pharmaceuticals prepared by radiolabelling with Indium (^{111}In) Chloride Solution will be dependent on the specific pharmaceutical being used. Such information should be available from the manufacturer of the pharmaceutical to be radiolabelled.

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 10^{-1} mSv is administered these adverse events are expected to occur with a low probability.

Higher doses may be justified in some clinical circumstances.

4.9 Overdose

In the event of administration of an overdose of a radiopharmaceutical, the absorbed radiation dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body.

Action to be taken in the event of administration of an overdose of an indium [^{111}In]-labelled pharmaceutical will be available from the manufacturer of the pharmaceutical to be radiolabelled.