Package Leaflet: Information for the patient

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your referring doctor or your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

PoltechMBrIDA, 20 mg,
kit for radiopharmaceutical preparation
N-[2,4,6-trimethyl-3-bromacetanilid]iminodiacetic acid sodium salt

What is in this leaflet

1. What PoltechMBrIDA is and what it is used for
This medicine is a radiopharmaceutical product for diagnostic use only.
PoltechMBrIDA after labelling with radioactive isotope of technetium (^{99m}Tc) is used for hepatobiliary imaging.

The use of PoltechMBrIDA does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before PoltechMBrIDA is used
PoltechMBrIDA must not be used
PoltechMBrIDA must not be used if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Take special care with PoltechMBrIDA
- if you are pregnant or believe you may be pregnant,
- if you are breastfeeding.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spill of urine, vomiting etc. Therefore basic hygiene rules should be observed according to national regulations.

Special caution should be exercised while handling, to avoid unnecessary radiation exposure to staff and patients.

The hepatic ducts may not be well visualized in the following cases:
- parenteral nutrition
- prolonged dieting (longer than 24 h)
- after a meal (the patient examination should be performed not less than 2 h, but preferably 6 h after the last meal)
- severe liver damage.

Children and adolescents
Talk to your nuclear medicine doctor if you are under 18 years old.
The use of product in children has to be considered carefully based upon clinical needs and assessment of the risk/benefit ratio in this patient group.

Other medicines and PoltechMBrIDA
Tell your doctor or nuclear medicine doctor who will supervise the procedure if you are taking or have recently taken or might take any other medicines.
Opiate analgesics may affect the flow of radiopharmaceutiacal in extrahepatic common bile duct. Morphine sulphate is commonly used to augment the bile flow into the gall bladder.
Cholecystokinin and its analogs cause the gall bladder to contract, thereby reducing the radiotracer flow into it. Fat meals and some food supplements may also stimulate gall bladder contraction.
In patients parenterally feeded or fasting for 24-48h intraluminal pressure in the gall bladder may rise, which prevents entry of the radiopharmaceutical.
Phenobarbital and ursodeoxycholic acid enhance biliary excretion of the radiotracer.
Other pharmaceuticals known to affect gall bladder or bile ducts or change ^{99m}Tc-IDA biodistribution are listed below.

Atropine
Benzodiazepine
Erythromycin
Estrogen
Ethanol
Glyceryl trinitrate
Glucagon
Naloxone
Nicotine
Nifedipine
Nicardipine
Nitric oxide
Pancreatic enzymes
Pirenzepine
Progesterone
Prostigmine
Somatostatine analogs
Theophylline

In patients receiving chemotherapy (anticancer medicines) via an indwelling hepatic artery catheter gall bladder visualization may be adversely affected during examination with ^{99m}Tc-MBrIDA.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given this medicine.
You must inform the nuclear medicine doctor before the administration of PoltechMBrIDA if:
- there is possibility you might be pregnant,
- you have missed your period,
- you are breastfeeding.

When in doubt, it is important to consult your doctor or the nuclear medicine doctor who will supervise the procedure.

If you are pregnant it is important to tell it your doctor. The use of radiopharmaceuticals during pregnancy should be considered carefully. The nuclear medicine doctor will only administer this product during pregnancy if a benefit is expected which would outweigh the risks.

If you are breastfeeding, and if the administration of radiopharmaceutical is considered necessary, your doctor can ask you to interrupt breastfeeding and to remove the milk from the breasts. Breastfeeding should be stopped for 4 hours after injection and the milk secreted during this period of time should be discarded. Please ask your nuclear medicine doctor when you can resume breastfeeding.

Driving and using machines
There are no studies on effect on your ability to drive or to use machines.

PoltechMBrIDA contains sodium
Inform your doctor if you are on low sodium diet.

3. How PoltechMBrIDA is used
Radiopharmaceuticals may be administered only by authorized health-care personnel.
There are strict laws on the use, handling and disposal of radiopharmaceutical products. PoltechMBrIDA will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

This product is for intravenous use.

The nuclear medicine doctor supervising the procedure will decide on the quantity of product to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered, recommended for an adult ranges between 111 and 185 MBq (megabecquerel, the unit used to express radioactivity). However other activities may also be used in case of higher level of bilirubin in blood.

Use in children and adolescents
In children and adolescents, the quantity to be administered will be adapted to the child's weight.

Administration of PoltechMBrIDA and conduct of the procedure
The ready to use solution for injection will be injected into a vein before the scan is taken.

Radioactive ^{99m}Tc-MBrIDA preparation is designed for intravenous use only under a close supervision of specialized personnel.

The safety regulations regarding work in the conditions of ionising radiation exposure should be strictly complied with during the preparation and administration of a radiopharmaceutical.

It is recommended to fast for 6-24 h before administration (depending on indications the time may be different) and avoid taking preparations which may affect the results of examination.

Duration of the procedure
Your nuclear medicine doctor will inform you about the usual duration of the procedure.

After administration of PoltechMBrIDA, you should:
The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more PoltechMBrIDA than you should
An overdose is unlikely, because you will only receive a dose of product precisely controlled by the nuclear medicine doctor supervising the procedure. However in the case of an overdose your doctor may recommend that you drink plenty of fluids to remove the traces of radiopharmaceutical from your body.

Should you have any further questions on the use of PoltechMBrIDA, please ask your doctor or the nuclear medicine doctor who supervises the procedure.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Side effects with unknown frequency:
- Allergic reactions:
  If you have an allergic reaction when you are in hospital or a clinic having the scan, tell the doctor or nurse straight away.
  The signs may include: skin rash or itching or flushing, swelling of the face, difficulty in breathing.
  If any of the side effects above happen after you leave the hospital or clinic, go straight to the casualty department of your nearest hospital.

The administered radiopharmaceutical will deliver low amount of ionising radiation associated with the least risk of cancer and hereditary abnormalities. For diagnostic nuclear medicine investigations the current evidence suggests that these adverse reactions are expected to occur with a low probability.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system.

Adverse reactions may be reported to Marketing Authorization Holder.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How PoltechMBrIDA is stored
You will not have to store this medicine.
This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

PoltechMBrIDA must not be used after the expiry date which is stated on the label.

6. Contents of the pack and other information
What PoltechMBrIDA contains
- The active substance is N-[2,4,6-trimethyl-3-bromacetanilid] iminodiacetic acid sodium salt
- The other ingredients are: stannous chloride dihydrate, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment)

What PoltechMBrIDA looks like and contents of the pack
Kit for radiopharmaceutical preparation.
White powder.
Product is delivered in 10 ml glass vials sealed with a rubber stopper and an aluminium cap packed in a cardboard box.
Pack sizes:
3 vials or 6 vials.
Each vial contains lyophilisate for solution for injection.

Marketing Authorisation Holder and Manufacturer
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For any more detailed information about this medicine, please contact your doctor or the local representative of the Marketing Authorisation Holder.

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The complete SmPC of PoltechMBrIDA is provided as a tear-off sectional the end of the printed leaflet in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical. Please refer to the SmPC.