

PART III: CONSUMER INFORMATION

CanTrace™

¹⁸F-Fluorodeoxyglucose, ¹⁸F-FDG

This leaflet is part III of a three-part "Product Monograph" published when CanTrace was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CanTrace. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

This medication is a radioactive tracer which is used as part of a nuclear medicine test called a Positron Emission Tomography (PET) scan, to help your doctor evaluate your cancer.

What it does:

CanTrace is a sugar molecule that has a radioisotope, Fluorine-18 attached to it. When CanTrace is injected into your vein, it will go to sites in your body where sugar is required. Cancer cells require lots of sugar to grow, so CanTrace will concentrate in them. The radioactive part of CanTrace (Fluorine-18) allows a picture to be taken using a Positron Emission Tomography (PET) camera that tells your doctor if you might have these cells, where they are in your body and / or to look at other features of your cancer.

When it should not be used:

- If you are pregnant or breast feeding.
- If you are allergic to any of the components of CanTrace.
- If you are diabetic and your blood sugar is not controlled.

What the medicinal ingredient is:

¹⁸F-Fluorodeoxyglucose (radioactive sugar-like molecule)

What the important nonmedicinal ingredients are:

Sodium Chloride (salt) and Water

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- § **Because CanTrace is a radiopharmaceutical, it can only be given by doctors and other health professionals who are specially trained and experienced in the safe use and handling of radioisotopes.**
- § **CanTrace should not be given to pregnant women unless it is considered that the benefits to be gained outweigh the potential hazards to the fetus**
- § **CanTrace can be passed into breast milk during nursing. To avoid unnecessary radiation exposure to your baby, formula feeding should be substituted temporarily for breast feeding.**

BEFORE you receive CanTrace talk to your doctor or pharmacist if:

- you have diabetes as special attention will be needed to assess your blood glucose levels prior to having a PET scan with CanTrace
- there is a possibility that you may be pregnant
- you are breast feeding your baby
- you think you have any allergies to any of the components in CanTrace

To decrease the radiation exposure to your bladder, you should drink plenty of water and urinate as often as possible when the PET scan is finished.

INTERACTIONS WITH THIS MEDICATION

It is not known whether drugs, food or natural health products interact with CanTrace.

PROPER USE OF THIS MEDICATION

This product (CanTrace) will be administered under the supervision of a health professional who is experienced in the use of radiopharmaceuticals.

You may also be asked to fast for 4 to 6 hours (nothing to eat but allowed to drink water) before you have a PET scan with CanTrace.

Diabetic patients should stabilise their blood glucose levels the day preceding and on the day of the PET scan.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

No side effects associated with the use of CanTrace have been identified in clinical trials.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

There are no known serious side effects with the use of CanTrace. If you experience any unusual effects after receiving CanTrace, contact your doctor or pharmacist. For example, symptoms of an allergic reaction would include rash, hives, itching, or fast heartbeat, nausea and vomiting.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadtmp@hc-sc.gc.ca

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness

Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph prepared for health professionals can be found at:

http://www.hc-sc.gc.ca/hpfb-dgpsa/bgtd-dpbtg/aboutus_e.html

<http://www.petscan.ca>

or by contacting the sponsor, IPET Pharmaceuticals, Inc., at:
1-604-689-7776

This leaflet was prepared by IPET Pharmaceuticals, Inc.

Last revised: July 24, 2006.