HOW SUPPLIED

Each HICON™ kit of 9.25 GBq (250 mCi) includes:

- a) a blister package of ten small hard gelatin capsules each containing approximately 300 mg of Dibasic Sodium Phosphate Anhydrous USP as absorbing buffer.
- b) a blister package of ten empty large hard gelatin capsules.
- c) a 1 mL vial containing 0.25 mL of Sodium lodide I 131 Solution USP, therapeutic oral solution containing approximately 9.25 GBq (250 mCi) at time of calibration.

Each HICON™ kit of 18.5 GBq (500 mCi) includes:

- a) two blister packages of ten small hard gelatin capsules each containing approximately 300 mg of Dibasic Sodium Phosphate Anhydrous USP as absorbing buffer.
- b) two blister packages of ten empty large hard gelatin
- c) a 1 mL vial containing 0.5 mL of Sodium lodide I 131 Solution USP, therapeutic oral solution containing approximately 18.5 GBq (500 mCi) at time of calibration.

Each HICON™ kit of 37 GBq (1,000 mCi) includes:

- a) four blister packages of ten small hard gelatin capsules each containing approximately 300 mg of Dibasic Sodium Phosphate Anhydrous USP as absorbing buffer.
- b) four blister packages of ten empty large hard gelatin capsules.
- c) a 1 mL vial containing 1 mL of Sodium Iodide I 131 Solution USP, therapeutic oral solution containing approximately 37 GBq (1,000 mCi) at time of calibration.

Each mL of the aqueous product that comes with HICON $^{\text{TM}}$ contains:

- 37 gigabecquerels of Sodium Iodide I-131
- < 2.0 mg of Disodium Edetate Dihydrate USP
- < 4.4 mg of Sodium Thiosulphate Pentahydrate USP
- < 40 mg of Dibasic Sodium Phosphate Anhydrous USP

Complete assay data are available on the container.

STORAGE

The Sodium Iodide I 131 Solution USP provided with HICON™ should be stored between 2° C and 25° C (36° F and 77° F).

NDC 65174-880-25 (for 250 mCi vial size) NDC 65174-880-50 (for 500 mCi vial size) NDC 65174-880-00 (for 1,000 mCi vial size)

Manufactured by: DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc., Kirkland, Québec, Canada.

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HOW SUPPLIED

Each HICON® kit of 9.25 GBq to 37 GBq (250 mCi to 1,000 mCi) includes:

- a) A minimum of one blister package of ten small hard gelatin capsules each containing approximately 300 mg of Dibasic Sodium Phosphate Anhydrous USP as absorbing buffer.
- A minimum of one blister package of ten empty large hard gelatin capsules.
- c) A 1 mL vial containing 0.25 mL to 1 mL of Sodium Iodide I 131 Solution USP, therapeutic oral solution containing approximately 9.25 GBq to 37 GBq (250 mCi to 1,000 mCi) at time of calibration.

Each mL of the aqueous product that comes with HICON® contains:

- 37 gigabecquerels of Sodium Iodide I-131
- < 2.0 mg of Disodium Edetate Dihydrate USP
- < 22 mg of Sodium Thiosulphate Pentahydrate USP
- < 40 mg of Dibasic Sodium Phosphate Anhydrous USP

Complete assay data are available on the container.

 Note that not all filled volumes/radioactivity within the range may be commercially available

STORAGE

The Sodium Iodide I 131 Solution USP provided with HICON® should be stored between 2° C and 25° C (36° F and 77° F).

NDC 65174-880-25 (for 250 mCi vial size) NDC 65174-880-50 (for 500 mCi vial size) NDC 65174-880-00 (for 1,000 mCi vial size)

Product No.:

502880-2: 250 mCi in 250 μ L 502880-5: 500 mCi in 500 μ L 502880-0: 1 000 mCi in 1 000 μ L

Manufactured by: Jubilant DraxImage Inc. Kirkland, Québec H9H 4J4, Canada. Revised February 2013 Printed in Canada 50000000560

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