CONTRAINDICATIONS

- Pregnancy: Use only when clearly needed. (8.1)

- Use cautiously in patients due to possible decreased renal function. (8.5)

- Use only with the knowledge of and under the supervision of qualified health care professionals. (8.9)

- The use of radiopharmaceuticals. (8.10)

- See 17 for PATIENT COUNSELING INFORMATION.

- To report SUSPECTED ADVERSE REACTIONS, contact Jubilant.

- HICON® is available in 1 mL size, clear vials containing a colorless, aqueous, concentrated Sodium Iodide I 131 Solution [9,250 MBq, containing approximately 300 mg of dibasic sodium phosphate anhydrous as the absorbing buffer are supplied along with HICON ® for the use in the preparation of Sodium Iodide I 131 Capsules or Solution. (9)

- The Recommended diluent is Purified Water containing 3700 to 7400 MBq (100 to 200 mCi) of HICON®.

- The recommended dose is 1100 to 3700 MBq (30 to 100 mCi) for orally administered sodium iodide I 131 capsules or solution is based on the thyroid gland uptake percentages in an average adult (73.7 kg reference model).

- The stated dosimetric parameter values are to be used for planning purposes only and are not intended to be used as a treatment plan. (8.16)

- Table 1 is not intended to be used for treatment planning. (8.16)

- Table 1 shows a range of uptake percentages in an average adult (73.7 kg reference model). (8.16)

- Associated with thyroid uptake of iodide I 131 depend on the uptake percentages in each organ. (8.16)

- Table 1*:

<table>
<thead>
<tr>
<th>Organ</th>
<th>Low uptake**</th>
<th>Medium uptake**</th>
<th>High uptake**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain</td>
<td>0.021</td>
<td>0.093</td>
<td>0.13</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.053</td>
<td>0.10</td>
<td>0.13</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.017</td>
<td>0.056</td>
<td>0.067</td>
</tr>
<tr>
<td>Adrenals</td>
<td>0.013</td>
<td>0.038</td>
<td>0.041</td>
</tr>
<tr>
<td>Joints</td>
<td>0.010</td>
<td>0.026</td>
<td>0.024</td>
</tr>
<tr>
<td>Liver</td>
<td>0.004</td>
<td>0.013</td>
<td>0.011</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.004</td>
<td>0.013</td>
<td>0.011</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.004</td>
<td>0.013</td>
<td>0.011</td>
</tr>
<tr>
<td>Rectum</td>
<td>0.004</td>
<td>0.013</td>
<td>0.011</td>
</tr>
<tr>
<td>Prostate</td>
<td>0.004</td>
<td>0.013</td>
<td>0.011</td>
</tr>
<tr>
<td>Bladder</td>
<td>0.004</td>
<td>0.013</td>
<td>0.011</td>
</tr>
<tr>
<td>Thyroid</td>
<td>2.2 280#</td>
<td>430# 580#</td>
<td>830# 1300#</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.54</td>
<td>0.45</td>
<td>0.39</td>
</tr>
<tr>
<td>Lymph nodes</td>
<td>0.056</td>
<td>0.054</td>
<td>0.052</td>
</tr>
<tr>
<td>Ureters</td>
<td>0.052</td>
<td>0.054</td>
<td>0.052</td>
</tr>
<tr>
<td>Spinal cord</td>
<td>0.052</td>
<td>0.054</td>
<td>0.052</td>
</tr>
<tr>
<td>Sigmoid colon</td>
<td>0.052</td>
<td>0.054</td>
<td>0.052</td>
</tr>
<tr>
<td>Large intestine wall</td>
<td>0.052</td>
<td>0.054</td>
<td>0.052</td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>0.54</td>
<td>0.45</td>
<td>0.39</td>
</tr>
<tr>
<td>Small intestine</td>
<td>0.39</td>
<td>0.34</td>
<td>0.29</td>
</tr>
<tr>
<td>Total body</td>
<td>2900</td>
<td>4300</td>
<td>5800</td>
</tr>
</tbody>
</table>

- Radiation exposure of breast tissue with lactation: Sodium iodide I 131 may cause radiation induced toxicities to the breast, with radiation sickness, sialadenitis, salivary gland dysfunction, bone marrow depression, lacrimation.

- Patients receiving concurrent anti-thyroid therapy. (4)

- Instruct patients to hydrate before and after administration of sodium iodide I 131. (2.2)

- Instruct patients to maintain a low-iodide diet two weeks prior to and during the course of sodium iodide I 131 therapy. (2.2)

- Patients should not be used as they may cause the pH to drop. (2.5)

- Patients with vomiting and diarrhea should be used to determine a safe sodium iodide I 131 activity to help deplete the thyroid hormone. Discontinue medication to help deplete the thyroid hormone, which may aggravate hyperthyroidism and thyroid crisis, acute leukemia, solid cancer. (6)

- In patients who show leukopenia or thrombocytopenia, three days before administration of sodium iodide I 131. (2.2)

- For a thyroid blocked from iodide uptake in the production of thyroid hormone. Table 1 shows a range of uptake percentages in an average adult (73.7 kg reference model). (8.16)

- Associated with thyroid uptake of iodide I 131 depend on the uptake percentages in each organ. (8.16)

- The stated dosimetric parameter values are to be used for planning purposes only and are not intended to be used as a treatment plan. (8.16)

- Table 1 is not intended to be used for treatment planning. (8.16)

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5.4 Fetal Toxicity

5.3 Hypersensitivity Reactions

occur in relation with excipients or chemical component of the patients who receive sodium iodide I\textsubscript{131}. Although iodide is status of females of reproductive potential prior to initiating contact with others, especially pregnant women and children, HICON® is contraindicated in lactating women because sodi-

6 ADVERSE REACTIONS

Many drugs and iodide-containing foods interfere with the

Respiratory, thoracic and mediastinal disorders: **radiation

Eye disorders: lacrimal gland dysfunction.

Hematologic and lymphatic disorders including fatalities:

Cardiac disorders: chest pain, tachycardia.

Gastrointestinal disorders: sialadenitis, salivary gland dys-

** In patients with iodide-avid lung metastases

** In patients with iodide-avid brain metastases

Concomitant use of bone marrow depressants may enhance

Nervous system disorders: headache, *cerebral edema.

Onset of symptoms may be delayed by several days to weeks

in Specific Populations (8.3)

Radiation therapy is recommended if hypothyroidism

is estimated at 37,000 MBq (250 mCi), 18,500 MBq (500 mCi), and

Gamma-14 81.2% 364.5

Gamma-14 81.2% 364.5

Days Fraction

9 .461 20 .179

10 OVERDOSAGE

Sodium iodide I\textsubscript{131} capsules, therapeutic.

Reproduced in clinical trials.

The relationship between the extent of iodide I\textsubscript{131} exposure

with local or pharmacologic effects has not been explored in clinical

Fertility may be impaired with HICON® treatment. Discuss

sperm banking for males who are expected to receive a high

Infants exposed to sodium iodide I\textsubscript{131} through breast milk are

administration of sodium iodide I\textsubscript{131}

radiation dose to the breast tissue, breastfeeding and breast-

should not breastfeed. In addition, to minimize the absorbed

administered in the postpartum period, the lactating mother

[see Warnings and Precautions (5.5)]

If sodium iodide I\textsubscript{131} is

[see Contraindications (4), Warnings and Precautions

[see Data]

Table 6

Table 4

[see Contraindications (4), Warnings and

[see Data]

Table 3

Table 2

Table 1

[see Data]

Table 1

[see Data]

Table 1

[see Data]

Table 1