IOSAT 65MG TABLETS
PL 10772/0001

UKPAR

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LAY SUMMARY

The MHRA granted a licence for the medicinal product Iosat 65mg Tablets (PL 10772/0001) to Agropharm Limited on 2 August 2012. Iosat 65mg Tablets is a Pharmacy medicine (legal status ‘P’). It is used to prevent absorption of radioactive iodine in the event of a nuclear accident.

This product contains the active substance potassium iodide. When nuclear accidents occur, radioactive iodine may be released. Radioactive iodine is similar to the natural iodine found in food, and can be stored in the thyroid gland in the same way. Iosat 65mg Tablets work by saturating the thyroid with iodine, therefore, preventing the absorption of radioactive iodine.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Iosat 65mg Tablets (PL 10772/0001) outweigh the risks, hence a Marketing Authorisation has been granted.
IOSAT 65MG TABLETS
PL 10772/0001

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation for the medicinal product Iosat 65mg Tablets (PL 10772/0001) to Agropharm Limited on 02 August 2012. Iosat 65mg Tablets is a Pharmacy medicine (legal status ‘P’), indicated for for thyroid iodine uptake blockade in nuclear accidents (to prevent accumulation of radioactive iodine (iodine 131) in the thyroid gland).

This application was submitted as a generic application, according to Article 10.1 of Directive 2001/83/EC, claiming to be a generic medicinal product of Kaliumiodid “Lannacher” 65mg Tabletten (Lannacher Heilmittel GmbH). The originator product was granted as an Article 10a application (well-established use) using bibliographic references. The current formulation of potassium iodide tablets has been available and licensed in the USA since 1982, based on a 130mg strength tablet.

This product contains the active substance potassium iodide. Potassium iodide when administered by oral administration is used as a thyroid-blocking medicine in nuclear radiation emergencies. In the event of a nuclear accident, the major public risk is likely to result from the release and dispersion of volatile radio-iodines. Upon body exposure and food ingestion, these radio-iodines are concentrated in the thyroid, resulting in substantial thyroidal irradiation and accordingly thyroid cancers. Stable potassium iodide (KI) effectively blocks thyroid iodine uptake. The efficiency of KI is directly related to the physiological inhibition of the thyroid function in the presence of high plasma iodide concentrations. This regulation is called the Wolff-Chaikoff effect. However, to be fully effective, KI should be administered shortly before or immediately after radioiodine exposure, as the level of blockade reduces with time when KI is administered after exposure. However, Iodine tablets can still reduce the amount of time for which radioactive iodine remains in the body, even when taken several hours after the radioactive iodine uptake.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place at all sites responsible for the manufacture and assembly of this product.

The marketing authorisation holder has provided the following reason for not submitting a bioequivalence study:

“The product, potassium iodide 65mg tablets, is an immediate-release tablet indicated for use in nuclear emergencies to prevent the uptake of radioactive iodines in the thyroid.” “This formula of potassium iodide tablet has been available and licensed in the US since 1982 based on a 130mg strength tablet. This 65mg strength product which received US approval in May 2011 has been developed in line with the European reference product. Comparative dissolution testing has shown equivalence of this product to the EU reference product, Kaliumiodid “Lannacher” 65mg tabletten. Based on the results of the comparative dissolution it was considered that bioequivalence testing was not required, as >85% dissolution was achieved within 15 minutes - EU guidance (CPMP/EWP/QWP/1401/98) notes that dissolution profiles may be considered to be equivalent and no further analysis is required if this criteria is met.”
The reason is accepted and a bioequivalence study is not considered necessary for this application.
**PHARMACEUTICAL ASSESSMENT**

**DRUG SUBSTANCE**
**Potassium Iodide**

INN: Potassium Iodide  
Chemical name: Potassium Iodide (Kalii iodidum)  
Molecular formula: KI  
Molecular weight: 166  
Appearance: A white to almost white powder. Very soluble in water, freely soluble in glycerol, soluble in ethanol (96%).

Potassium Iodide is the subject of a European Pharmacopoeia monograph.

Synthesis of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specification.

Batch analysis data are provided and comply with the proposed specification.

Specifications have been provided for all packaging used. All primary packaging meet the requirements of current European Directives concerning contact with food.

Based on stability studies, a suitable retest period has been proposed for the active substance.

**DRUG PRODUCT**
**Other ingredients**

Other ingredients consist of pharmaceutical excipients, namely microcrystalline cellulose, sodium thiosulfate, colloidal anhydrous silica and magnesium stearate. All excipients comply with their respective European Pharmacopoeia monograph.

None of the excipients use materials sourced from animal or human origins. None of the excipients are sourced from genetically modified organisms.

**Product development**
The objective of the pharmaceutical development programme was to produce a safe, efficacious tablet formulation that could be considered a generic medicinal product of Kaliumiodid “Lannacher” 65mg Tabletten (Lannacher Heilmittel GmbH).

The applicant has provided a suitable product development section. Justifications for the use and amounts of each excipient have been provided and are valid. Comparative dissolution profiles of the proposed product and the originator product have been provided and are satisfactory.
Manufacture
A description and flow-chart of the manufacturing method have been provided.

In-process controls are satisfactory based on process validation data and controls on the finished product. Process validation has been carried out on batches of finished product and the results appear satisfactory.

Finished product specification
The finished product specification is satisfactory. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis for all working standards used have been provided and are satisfactory.

Container-Closure System
The finished product is packaged in aluminium/low-density polyethylene blister strips in packs containing either 20 or 100 tablets.

Specifications and Certificates of Analysis for all packaging have been provided. These are satisfactory. The EU Directive 2005/79/EC (regarding the contact of materials with foodstuff) does not directly apply to the primary container, however the material complies with the European Pharmacopoeia 6th Edition – Supplement 6.0 “3.1.3 Polyolefins” and the intermediate materials comply with the EU Regulation 10/2011/EC (PIM) on plastic materials that contact food.

Stability
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 5 years has been set, with the storage instructions ‘Store in the original container to protect from light. Store below 30°C’.

ADMINISTRATIVE
Expert Report
A pharmaceutical expert report has been written by a suitably qualified person and is satisfactory.

Summary of Product Characteristics (SmPC)
This is pharmaceutically satisfactory.

Labelling
These are pharmaceutically satisfactory.

Patient Information Leaflet (PIL)
This is pharmaceutically satisfactory.

The results of the PIL user testing have been submitted. These indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.
MAA Form
This is pharmaceutically satisfactory.

Conclusion
It is recommended that a Marketing Authorisation is granted for this application.
NON-CLINICAL ASSESSMENT

As the pharmacodynamic, pharmacokinetic and toxicological properties of potassium iodide are well-known, no further non-clinical studies are required and none have been provided.

The applicant’s non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the product’s pharmacology and toxicology.

A human health and environmental review, submitted by the Environmental Protection Agency (EPA) for iodine and iodophor complexes has been submitted. It concludes that the active ingredient of this product does not present a significant new environmental risk.

There are no objections to the approval of this product from a non-clinical viewpoint.
CLINICAL ASSESSMENT

Pharmacokinetics
The marketing authorisation holder has provided the following reason for not submitting a bioequivalence study:

“The product, potassium iodide 65mg tablets, is an immediate-release tablet indicated for use in nuclear emergencies to prevent the uptake of radioactive iodines in the thyroid.” “This formula of potassium iodide tablet has been available and licensed in the US since 1982 based on a 130mg strength tablet. This 65mg strength product which received US approval in May 2011 has been developed in line with the European reference product. Comparative dissolution testing has shown equivalence of this product to the EU reference product, Kaliumiodid “Lannacher” 65mg tabletten. Based on the results of the comparative dissolution it was considered that bioequivalence testing was not required, as >85% dissolution was achieved within 15 minutes - EU guidance (CPMP/EWP/QWP/1401/98) notes that dissolution profiles may be considered to be equivalent and no further analysis is required if this criteria is met.”

The reason is accepted and a bioequivalence study is not considered necessary for this application.

Efficacy
No new data on the efficacy have been submitted and none are required for this application.

Safety
No new safety data were submitted and none were required.

SmPC, PIL and Labels
The SmPC, PIL and labels are medically acceptable. The SmPC is consistent with that for the originator product.

Clinical Expert Report
The clinical expert report has been written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.

Conclusion
The grant of a marketing authorisation is recommended.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The important quality characteristics of Iosat 65mg Tablets (PL 10772/0001) are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type. A human health and environmental review, submitted by the Environmental Protection Agency (EPA) for iodine and iodophor complexes has been submitted. It concludes that the active ingredient of this product do not present a significant new environmental risk.

CLINICAL
No bioequivalence study has been submitted with this application and none was required. Bioequivalence between Iosat 65mg Tablets and the originator product Kaliumiodid “Lannacher” 65mg Tabletten (Lannacher Heilmittel GmbH) was shown through comparable dissolution data.

No new or unexpected safety concerns arose from this application.

The SmPC, PIL and labelling are satisfactory and consistent with those for the originator product.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The dissolution data submitted support the claim that the applicant’s product and the originator product are interchangeable. Extensive clinical experience with potassium iodide is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is therefore considered to be positive.
IOSAT 65MG TABLETS
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STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the marketing authorisation application on 16 June 2007

2. Following standard checks and communication with the applicant the MHRA considered the application valid on 30 June 2009

3. Following assessment of the application, the MHRA requested further information on 13 May 2009, 08 June 2009, 02 August 2010, 27 February 2012 and 15 June 2012

4. The applicant responded to the MHRA’s requests, providing further information on 08 June 2009, 04 August 2009, 02 December 2011, 14 May 2012 and 18 June 2012

5. The application was determined on 27 July 2012
## IOSAT 65MG TABLETS
PL 10772/0001

### STEPS TAKEN AFTER AUTHORISATION - SUMMARY

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
</table>

1 **NAME OF THE MEDICINAL PRODUCT**
Iosat 65mg tablets

2 **QUALITATIVE AND QUANTITATIVE COMPOSITION**
Each Iosat tablet contains 65mg potassium iodide, equivalent to 50mg iodine.
For the full list of excipients, see section 6.1.

3 **PHARMACEUTICAL FORM**
Tablet.
White rounded tablet of 5 mm diameter with “IOSAT” on one side and quadrasect on the other side.

4 **CLINICAL PARTICULARS**

4.1 **Therapeutic indications**
Iosat 65mg Tablets are used for thyroid iodine uptake blockade in nuclear accidents (to prevent accumulation of radioactive iodine (iodine 131) in the thyroid gland).

4.2 **Posology and method of administration**
Take only when instructed by a physician or the authorities.

The tablets can be swallowed or dissolved in a small amount of liquid before being taken. Potential irritation of the gastric mucosa can be avoided by drinking plenty of additional fluids. To obtain the correct dosage for children aged up to 36 months, a solution should be prepared using a whole tablet, and the required volume of solution given (see details later in this section on making a potassium iodide solution).

The iodine blockade achieved with doses in the order of 100 mg or more of iodide results in reduced uptake of radioactive iodine by the thyroid gland by a factor of 90 or more, provided that the tablets are taken promptly. If possible, the iodine tablets should be taken before any radioactive iodine uptake occurs. Satisfactory blockade can still be achieved provided the radioactive iodine uptake has occurred less than two hours previously. Iodine tablets can still reduce the amount of time for which radioactive iodine remains in the body, even when taken several hours after the radioactive iodine uptake.

The tablets should however be taken for the first time no later than one day after radioactive iodine uptake, as otherwise its elimination is delayed.

<table>
<thead>
<tr>
<th>Population/age group</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant and breast-feeding women:</td>
<td>2 tablets (equivalent to 100 mg iodine)</td>
</tr>
<tr>
<td>&lt; 1 month:</td>
<td>¼ tablet (equivalent to 12.5 mg iodine)</td>
</tr>
<tr>
<td>1 to under 36 months:</td>
<td>½ tablet (equivalent to 25 mg iodine)</td>
</tr>
<tr>
<td>3 to under 13 years:</td>
<td>1 tablet (equivalent to 50 mg iodine)</td>
</tr>
<tr>
<td>13 to under 45 years:</td>
<td>2 tablets (equivalent to 100 mg iodine)</td>
</tr>
<tr>
<td>Persons over 45 years:</td>
<td>Tablet intake is not recommended</td>
</tr>
</tbody>
</table>

A single dose is generally sufficient. In exceptional cases, the competent authorities or a physician will recommend that an additional tablet be taken.

However, dosing must always be limited to 1 day for neonates and to 2 days for women who are pregnant or breast-feeding.

A solution of potassium iodide should be prepared in order to administer a partial-tablet dose to children under 36 months.

Making a Potassium Iodide Solution:
1. Put one tablet into a small bowl and grind it into a fine powder using the back of a metal teaspoon against the inside of the bowl. The powder should not have any large pieces.
2. Add 4 teaspoonfuls of water to the crushed potassium iodide powder in the bowl and mix until the powder is dissolved in the water.
For children < 1 month old, administer 1 teaspoonful.

For children from 1 to 36 months old, administer 2 teaspoonfuls

The dose may be given mixed with a small amount of flavoured drink in order to make it more palatable for the child.

4.3 Contraindications

Iosat 65mg tablets must not be used in patients with:

- Hyperthyroidism of any aetiology
- Known hypersensitivity to iodine (this is very rare and must not be confused with the common allergy to x-ray contrast media) or to any of the excipients
- Duhring’s disease (dermatitis herpetiformis)
- Hypocomplementaemic vasculitis

4.4 Special warnings and precautions for use

Use of Iosat 65mg tablets in patients > 45 years

In an iodine-deficient region where the incidence of autonomous thyroid function increases with age with an accompanying increase in the risk of side effects from iodine blockade, and where the risk of radiation-induced thyroid cancer is considerably reduced with advancing age, iodine blockade is not recommended for individuals aged over 45.

Special precautions for the use of Iosat 65mg tablets

Patients already under treatment with thyrostatic drugs must continue with this treatment and undergo medical examinations at frequent intervals.

The administration of iodine should generally be avoided in patients with suspected thyroid cancer.

Patients with Duhring’s dermatitis herpetiformis or genuine iodine allergy (allergies to x-ray contrast media are frequently not allergies to iodine but rather to the contrast medium itself) must not undergo iodine blockade. Because the extent of the reactions in each individual case cannot be predicted, the long-term and indeterminate risk of irradiation of the thyroid gland must be considered as being lower than the immediate and potentially severe consequences of an allergic reaction.

Administration of large quantities of iodine may cause an increase in the size of the thyroid gland which may in turn exacerbate any pre-existing severe tracheal compression.

If autonomous areas are left untreated, there is a risk of hyperthyroidism which may in the most extreme cases provoke a thyrotoxic crisis. Iodine tablets should not therefore be taken in these cases.

4.5 Interaction with other medicinal products and other forms of interaction

Thyrostatic agents required to treat hyperthyroidism would exhibit reduced efficacy when taken concomitantly with Iosat 65mg tablets.

Iodine uptake in the thyroid gland is competitively inhibited by substances which enter the thyroid via the same “trapping” mechanism as iodine (e.g. perchlorate, which also inhibits the recirculation of iodine within the gland), as well as by substances which are not themselves transported (such as thiocyanate at concentrations over 5 mg/dl).

4.6 Fertility, pregnancy and lactation

Pregnant and breastfeeding women are given the same dose of Iosat 65mg tablets as adolescents and adults (see section 4.2, Posology and method of administration). The duration of treatment for pregnant and breastfeeding women should be limited to two days.

4.7 Effects on ability to drive and use machines

Potassium iodide is not expected to impair concentration or reactions.
4.8 Undesirable effects

The following frequency convention was used as a basis for evaluating undesirable effects:

- **Very common:** ≥ 1/10
- **Common:** ≥ 1/100, < 1/10
- **Uncommon:** ≥ 1/1,000, < 1/100
- **Rare:** ≥ 1/10,000, < 1/1,000
- **Very rare:** < 1/10,000, not known (cannot be estimated from the available data)

**Gastrointestinal disorders**

Common: Iosat 65mg tablets may cause irritation of the gastric mucosa, especially when taken on an empty stomach.

**Endocrine disorders**

Iosat 65mg tablets to prevent radioactive iodine accumulation may in isolated cases result in iodine-induced hyperthyroidism. In most cases, this is attributable to autonomous areas in the thyroid.

**Vascular disorders**

Rare: Periarteritis nodosa.

**Immune system disorders**

In rare cases, an undiagnosed iodine allergy may manifest itself for the first time when iodine tablets are taken. This may include general signs of allergy and in addition, due to increased secretion from the mucosa, itching and burning in the eyes, iodine-induced rhinitis, irritant cough, diarrhoea, headaches due to sinusitis, and other symptoms. Life-threatening reactions are possible, particularly in the case of pre-existing Duhring’s dermatitis herpetiformis.

4.9 Overdose

a) **Overdose:**

The administration of very high doses of iodide may result in irritation of the skin and mucous membranes (e.g. gastroenteritis). In the event of potentially life-threatening symptoms, gastric lavage is indicated, possibly followed by administration of an isotonic sodium sulfate solution as a laxative.

b) **Iodine-induced hypothyroidism:**

Discontinue iodine and restore the metabolic balance by administration of thyroid hormones.

c) **Iodine-induced hyperthyroidism:**

This is not strictly speaking an overdose since hyperthyroidism can also be triggered by levels of iodine that are considered to be physiological in other countries.

Treatment appropriate to the form of hyperthyroidism should be given.

In certain circumstances, mild forms may not require any treatment, while more severe forms may require thyrostatic therapy (although this is slow to take effect). In the most severe cases (thyrotoxic crisis), intensive care, plasmapheresis or thyroidectomy are indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antidote, potassium iodide.

ATC code: V03AB21

The effects of exogenous iodine administration on the human body depend on the daily iodine dose, the type of iodine product and the condition of the thyroid gland (healthy organ, latent disorder or manifest disorder).

Pharmacologically effective iodine doses (over 1 mg/day) can trigger the following effects:

a) Wolff-Chaikoff effect. Excess iodine results in inhibition of organification in the thyroid gland. If this excessive iodine level persists, inhibition is superseded by reduced
iodine uptake. Persistence of the Wolff-Chaikoff effect under pathological conditions results in hypothyroidism and the development of goitres.

b) Reduced intrathyroid iodine metabolism and colloid proteolysis and hence reduced hormone release. This effect is particularly marked in cases of hyperthyroidism, and is accompanied – in particular in patients with immunogenic forms of hyperthyroidism – by reduced perfusion, reduced size and induration of the thyroid gland.

5.2 Pharmacokinetic properties

Absorption
Iodine normally enters the body via the gastrointestinal tract. However, it is also absorbed percutaneously and from body cavities. Particular attention must be paid to this in cases of accidental iodine medication intake. Absorption of inorganic iodine in the small intestine is almost 100%; percutaneous absorption however is minimal and uncontrolled.

Distribution
The volume of distribution in healthy subjects averages 23 litres (38% of body weight). Serum levels of inorganic iodine are normally between 0.1 and 0.5 µg/dl. In the body, iodide accumulates in the thyroid gland and in other tissues, such as the salivary glands, mammary glands and the stomach. Iodine stored within the thyroid has a half-life of 7 weeks.

Biotransformation
Elimination
The elimination of iodine in the urine, which is expressed in most cases as µg/g creatinine, is used as an indicator of iodine intake as it is in equilibrium with daily dietary iodine intake.

Linearity/non-linearity
Pharmacokinetic/pharmacodynamics relationship(s)
The iodide concentration in the saliva, gastric juices and breast milk is approximately thirty times the plasma concentration.

5.3 Preclinical safety data

Mutagenic and carcinogenic potential
There are no known studies investigating mutagenic and carcinogenic potential. There are no indications that iodine or iodide possess such properties.

Reproductive toxicity
There is no evidence of teratogenic effects from animal studies. Iodine crosses the placenta and may cause foetal hypothyroidism and/or goitre when administered to pregnant women at very high doses. Iodide is concentrated in and excreted in breast milk. When administered at very high doses, there is a risk of infants developing hypothyroidism. Limiting the use of potassium iodide tablets in pregnant and breastfeeding women to a maximum of 2 days counters the potential risks for the foetus and infant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Cellulose, microcrystalline
Sodium thiosulfate
Silica, colloidal anhydrous
Magnesium stearate

6.2 Incompatibilities
None known.

6.3 Shelf life
5 years.

6.4 Special precautions for storage
Store in the original container to protect from light. Store below 30°C.
6.5 **Nature and contents of container**  
Iosat 65mg tablets are supplied in blister strips in packs containing either 20 or 100 tablets. Not all pack sizes may be marketed.

6.6 **Special precautions for disposal**  
Any unused product or waste material should be disposed of in accordance with local requirements.

7 **MARKETING AUTHORISATION HOLDER**  
Agropharm Limited  
Iosat Division  
Buckingham Place,  
Church Road, Penn,  
High Wycombe, Bucks,  
HP10 8LN, United Kingdom.

8 **MARKETING AUTHORISATION NUMBER(S)**  
PL 10772/0001

9 **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**  
02/08/2012

10 **DATE OF REVISION OF THE TEXT**  
02/08/2012
**UKPAR Iosat 10mg Tablets**

**Package Leaflet for Emergency Supplies**

**Iosat 65mg Tablets**

**This medicine should be taken if there is a radiation accident involving the release of radioactive iodine.**

Only take this medicine if a doctor tells you to.

Iosat tablets stop the thyroid gland from absorbing radioactive iodine.

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**Do not take this medicine if you have:**
- an over-active thyroid
- a known allergy to iodine or to any of the other ingredients
- a skin condition that causes blisters known as Duhning’s disease (dermatitis herpetiformis)
- an itchy skin rash known as hypocomplementaemic vasculitis

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**Package Leaflet:**

**Information For The User**

**Iosat 65mg Tablets**

Active substance: Potassium iodide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as instructed by a doctor or the competent authorities.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist.

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**What is in this leaflet:**

1. What Iosat tablets are and what they are used for
2. What you need to know before you take Iosat
3. How to take Iosat
4. Possible side effects
5. How to store Iosat
6. Contents of the pack and other information

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1. **What Iosat Tablets Are and What They Are Used For**

Iosat tablets contain the active substance potassium iodide. When nuclear accidents occur radioactive iodine may be released. Radioactive iodine is similar to the natural iodine found in food, and can be stored in your thyroid gland in the same way.

**Iosat works by saturating your thyroid with iodine.**

Your thyroid gland is therefore prevented from absorbing radioactive iodine.

**Iosat is used to stop you absorbing radioactive iodine in nuclear accidents.**

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2. **What You Need To Know Before You Take Iosat**

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**Do NOT take Iosat:**

- If you have an over-active thyroid.
- If you are allergic (hypersensitive) to iodine. This is very rare. Do not confuse it with the common allergy to what are called x-ray contrast media (medicines which enhance images of structures and functions in the body so that they can be seen more clearly, e.g. on x-rays).
- If you are allergic (hypersensitive) to any of the other ingredients of Iosat (see Section 6).
- If you suffer from a disease in which you develop blisters, reddening of the skin and eczema, mainly in the elbows or knees (Duhning’s dermatitis herpetiformis).
- If you know you have an allergy that causes inflammation of the blood vessel walls (hypocomplementaemic vasculitis).

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**Warnings and precautions**

- If you are over 45 years old, this medicine is not recommended for two reasons:
  - you have a higher risk of side effects from Iosat as you get older.
  - you are less likely to get thyroid cancer as you get older.
- If you have anything wrong with your wind pipe (trachea), this medicine may make it worse.
- If you have a benign nodule in your thyroid gland which is not being treated, taking this medicine may cause the thyroid to become over-active. If you know that you have an untreated nodule, you should not take Iosat.
- If you are taking medicine to treat an over-active thyroid, your doctor may want to examine you more often.
- If it is suspected that you have thyroid cancer you will not usually be given Iosat. Taking this medicine may make radiotherapy impossible. It may also make it hard to tell exactly what is wrong with your thyroid.

**Other medicines and Iosat**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

**Iosat and other medicines can affect each other such as:**

Medicines which stop your thyroid gland taking up so much iodine (e.g. perchlorate, thiocyanate in concentrations over 5 mg/dl) may prevent Iosat from working effectively.

Medicines that reduce the activity of your thyroid gland may not work as well.

**Iosat with food and drink**

Food and drink have no effect on how Iosat works.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, or think you may be pregnant, ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Iosat is not expected to affect your ability to drive or use machines.
3. How to take Iosat

Always take Iosat exactly as described in this leaflet or as your doctor or the competent authorities have told you. Check with your doctor or pharmacist if you are not sure.

The tablets are most effective if they are taken shortly before or at the same time as you breathe in radioactive iodine. Do not start taking Iosat more than one day after you are exposed to radioactive iodine. Starting the tablets then is likely to be harmful.

The usual dose is:
Please follow the directions for use exactly, or Iosat may not work properly.

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborn (less than 1 month)</td>
<td>¼ tablet (equivalent to 12.5 mg iodine)</td>
</tr>
<tr>
<td>1 month to under 36 months</td>
<td>½ tablet (equivalent to 25 mg iodine)</td>
</tr>
<tr>
<td>3 to under 13 years</td>
<td>1 tablet (equivalent to 50 mg iodine)</td>
</tr>
<tr>
<td>13 to 45 years</td>
<td>2 tablets (equivalent to 100 mg iodine)</td>
</tr>
<tr>
<td>Over 45 years</td>
<td>Not recommended</td>
</tr>
</tbody>
</table>

How to take the tablets
Swallow tablets whole or dissolve them in a small amount of liquid such as water. Drinking plenty of additional fluid may stop your stomach being irritated.

How to give the medicine to children under 36 months
To obtain the correct dose for children aged under 36 months, dissolve the tablet in water as described below.

1. Put one tablet into a small bowl and grind it into a fine powder using the back of a metal teaspoon against the inside of the bowl. The powder should not have any large pieces.
2. Add 4 teaspoonsfuls of water to the crushed powder and mix until the powder is dissolved in the water.

For children less than 1 month old, administer 1 teaspoonful.

For children from 1 to 36 months old, administer 2 teaspoonfuls.

In order to make it taste better for the child, you can add the dose to a small amount of flavoured drink and ensure that the child drinks the whole amount.

How long should you take Iosat tablets
You will usually take a single dose of Iosat. Sometimes an additional dose may be given. It is important that:
- Newborn infants only have one dose.
- Pregnant and breastfeeding women do not have more than two doses.

If you take more Iosat than you should
Taking very large quantities of iodide may result in skin irritation and stomach pains. The symptoms are similar to the side effects described in section 4. If you have severe problems, your doctor may need to pump your stomach.

4. Possible Side Effects

Like all medicines, Iosat can cause side effects, although not everybody gets them.

The side effects may be:
- Common: may affect up to 1 in 10 people
  - Irritation of the lining of your stomach may occur, especially if Iosat tablets are taken on an empty stomach.
- Rare: may affect up to 1 in 1,000 people
  - Inflammation of the blood vessels (e.g. periangiitis nodosa).
  - Allergic reaction such as redness of the skin, itching and burning in the eyes, runny nose, irritable cough, diarrhoea, headaches and similar symptoms. Life-threatening reactions are possible, particularly if you already suffer from Duhring's dermatitis herpetiformis, a disease which causes blisters, reddened skin and eczema, mainly in the elbows or knees (see section 2, "Do not take Iosat").
- Very rare: may affect up to 1 in 10,000 people
  - Iodine-induced over-active thyroid. Signs of an over-active thyroid may include problems such as a rapid pulse, sweats, difficulty in sleeping, shaking, diarrhoea and weight loss despite an increased appetite. If you experience problems like these, contact your doctor.

5. How To Store Iosat

Store in the original package in order to protect from light. Store below 30°C.

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the blister strip and carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents Of The Pack and Other Information

What Iosat tablets contain
- The active substance is potassium iodide. 1 tablet contains 65 mg potassium iodide.
- The other ingredients are: microcrystalline cellulose, sodium thiosulfate, colloidal anhydrous silica and magnesium stearate.

What Iosat looks like and contents of the pack
The tablets are white, round tablets with IOSAT on one side and a cross-shaped scoreline on the other side. Iosat is available in packs containing 20 tablets or 100 tablets.

Agropharm Ltd
Marketing Authorisation Holder
Agropharm Limited
IOSAT Division, Buckingham Place, Church Road, Penn, High Wycombe, Bucks, HP10 8LN United Kingdom.

Manufacturer
Wasdoll Packaging Limited
Unit 6, Euroway Industrial Estate, Blagrove, Swindon, Wiltshire, SN5 8WJ, United Kingdom.

This leaflet was last revised in July 2012.
UKPAR Iosat 10mg Tablets

20 Tablets

PL 10772/0001

IOSAT™ 65mg Tablets
Potassium iodide Ph. Eur.

Each tablet contains Potassium Iodide 65mg Ph. Eur. (Iodine 50mg)
Tablets for oral administration

20 Tablets

MARKETING AUTHORISATION HOLDER:
AgroPlant Limited, Iosat Division, Buckingham Place,
Church Road, Pinner, HP10 8LN, UK
Each tablet contains Potassium Iodide 65mg Ph. Eur. (Iodine 50mg)
Tablets for oral administration

100 Tablets