

USE OF IODINE TABLETS (65 mg potassium iodide per table) IN THE EVENT OF A NUCLEAR EMERGENCY LEAFLET INTENDED FOR THE PUBLIC

THE TABLETS MUST ONLY BE TAKEN ON ADVICE FROM THE AUTHORITIES WHEN THERE IS A RISK OF EXPOSURE TO RADIOACTIVE IODINE AND NEVER AT YOUR OWN INITIATIVE. THE TABLETS CONTAIN POTASSIUM IODIDE WHICH SATURATES THE THYROID GLAND WITH IODINE AND BLOCKS THE ABSORPTION OF RADIOACTIVE IODINE. AS SUCH, THE TABLETS HELP PREVENT THYROID CANCER.

1. WHO PRIMARILY BENEFITS FROM TAKING IODINE TABLETS IN THE EVENT OF A NUCLEAR EMERGENCY?

Children under 18 years of age, in particular the youngest of them, are at greatest risk in the event of a nuclear emergency. They are most likely to develop thyroid cancer following exposure to radioactive iodine. This increased sensitivity exists well before the birth of the child and explains why the use of iodine tablets is highly recommended for pregnant and breastfeeding women. Young adults aged between 18 and 40 are less sensitive than children and present a reduced risk. For persons over 40 years of age, please refer to point 9.

2. EMERGENCY SITUATIONS IN WHICH RADIOACTIVE IODINE IS RELEASED

In the event of a nuclear emergency at a nuclear power plant or elsewhere, it is possible that radioactive iodine will be released into the atmosphere, alongside other radioactive substances. If this is the case, you will be informed by the authorities who will provide instructions on taking iodine tablets.

3. HOW DOES RADIOACTIVE IODINE ENTER THE BODY?

Radioactive iodine can enter the body in one of three ways:

- By inhaling air that contains radioactive iodine. The danger of inhaling radioactive iodine may be partially reduced by remaining indoors, keeping doors and windows closed, and cutting off ventilation (air conditioning).
- By ingesting solid and liquid foodstuffs that contain radioactive iodine. The authorities take measures to prevent contaminated foodstuffs being consumed by the public by introducing, for example, a temporary ban on the consumption of milk, vegetables, etc.
- Through the skin. The level of absorption through the skin is usually negligible.

4. HOW DO IODINE TABLETS WORK?

A special characteristic of iodine (both radioactive and non-radioactive) is that it accumulates in the thyroid after it has been absorbed by the body. The thyroid needs a small amount of (non-radioactive) natural iodine to work correctly: this small amount (0.1 to 0.2 mg/day) usually comes from food. Accidental exposure to radioactive iodine also results in its absorption by the thyroid gland if measures to protect the thyroid, in other words iodine tablets, are not taken at the right moment. The iodine tablets in this packaging contain a large amount of natural iodine (in the form of 65 mg of potassium iodide per tablet). By taking these tablets, the thyroid gland becomes saturated with iodine. The saturated thyroid gland will then no longer be able to absorb radioactive iodine.

The iodine tablets only protect the thyroid against the effects of radioactive iodine, and not against other radioactive substances or external radiation. This is why iodine tablets are normally taken in addition to other preventative measures, such as confinement (staying indoors with doors and windows closed and ventilation - a/c - cut off) and avoiding ingesting contaminated food and drink.

5. WHEN SHOULD IODINE TABLETS BE TAKEN?

In the event of a nuclear emergency, the authorities will assess whether it is necessary to take iodine tablets and will inform you accordingly through messages broadcast on the radio, on television, by SMS or over loudspeakers. The thyroid gland is most effectively protected by absorbing iodine tablets shortly before or almost simultaneously to the exposure to radioactive iodine. If iodine tablets are taken too soon (more than 12 hours before exposure) or too late (just a few hours after exposure), less protection will be afforded. Iodine tablets no longer offer protection when taken more than 24 hours after exposure.

THE TABLETS MUST ONLY BE TAKEN ON ADVICE FROM THE AUTHORITIES AND NEVER AT YOUR OWN INITIATIVE. WATCH OR LISTEN TO THE MEDIA AND WAIT FOR ADVICE FROM THE AUTHORITIES.

6. HOW MANY IODINE TABLETS SHOULD BE TAKEN?

The number of tablets given in the Table below only applies to iodine tablets containing 65mg of potassium iodide, as is the case in this packaging.

THE RECOMMENDED DOSE MUST NOT BE EXCEEDED!

Table: Recommended potassium iodide dose and number of 65mg tablets to be taken depending on age

Age	Dose recommended daily (mg)	Number of 65mg tablets	Number of days
up to 1 month	16.25mg	1/4 tablet	single dose

from 1 month to 3 years	32.5mg	1/2 tablet	follow the instructions given by the authorities*
from 3 to 12 years	65mg	1 tablet	follow the instructions given by the authorities*
from 12 to 40 years	130mg	2 tablets	follow the instructions given by the authorities*
pregnant or breastfeeding women (regardless of age)	130 mg	2 tablets	follow the instructions given by the authorities*
over 40 years of age	consult your general practitioner or a specialist for information before a state of emergency occurs		

* If necessary, the authorities will recommend repeat dosing with iodine tablets, with potential changes to the dose.

Usually, a single dose of iodine tablets as recommended in the Table above should be sufficient. In case of repeated or prolonged exposure to radioactive iodine, please carefully follow the instructions given by the competent authorities who will be evaluating the situation on an hourly basis. If necessary, the authorities will advise you to continue taking iodine as listed in the table above in the day(s) following the event and will also keep you informed if a reduction of the aforementioned doses is indicated.

Newborns should be limited to taking a single dose. This is also the case for pregnant and breastfeeding women. The authorities will only recommend a second, usually weaker, dose under exceptional circumstances.

If you take medications to treat thyroid conditions, take the amount of iodine tablets recommended in the Table above and continue treatment of your thyroid problems as normal. You must consult your general practitioner as soon as the state of emergency has passed.

7. HOW SHOULD IODINE TABLETS BE TAKEN?

For young children (babies and children under 3 years of age) who are unable to swallow quarter or half a tablet as it is, the quarter or half-tablet must first be ground into a powder. This powder should be dissolved in a small amount of water (Figure A) which will then be mixed with a larger quantity of drink (Figure B), for example, water, fruit juice or (breast) milk. A solution prepared in this way cannot be stored and must be drunk immediately. If no drink is available, you can also add the powder to a child's meal. These young children cannot swallow a quarter or half-tablet whole.

From 3 years of age, it is also advisable to first dissolve the tablets in a small quantity of water (Figure A), which will then be mixed with a larger quantity of drink (Figure B). It is inadvisable to take iodine tablets with an alcoholic drink. If no drink is available, you can also swallow the tablet(s) whole, if possible alongside a small amount of food.

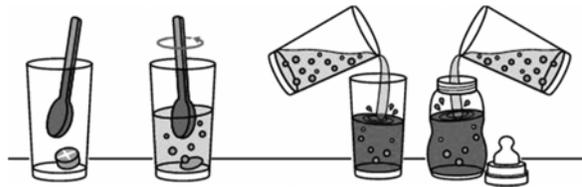


Figure A) First dissolve the recommended quantity of iodine tablet in a small quantity of water

Figure B) Add this solution to a larger quantity of drink, such as water, fruit juice or (breast) milk

8. IODINE TABLETS WHEN PREGNANT OR BREASTFEEDING

If you are pregnant, even if you are over 40 years of age, you must take the recommended quantity of tablets for an adult. The aim is to protect both you and your future baby. You should inform your doctor, so special attention can be paid to the results of the thyroid examination carried out on the newborn (a routine test carried out on all newborns).

If you are breastfeeding, even if you are over 40 years of age, you must take the recommended quantity of tablets for an adult. You can then continue breastfeeding as normal. The aim is to protect both you and your breastfed baby. The baby must also take his/her own iodine in the quantity given in the Table above (see point 6), by, for example, dissolving it in (breast) milk. Normally, women who are pregnant or breastfeeding only take a single dose of tablets. A second, usually weaker, dose will only be recommended by the authorities under exceptional circumstances.

The quantity of iodine present in multivitamins is NOT sufficient to saturate the thyroid gland and is therefore not considered an alternative to the taking of iodine tablets in this packaging.

9. IODINE TABLETS FOR PEOPLE OVER 40 YEARS OF AGE

The risk of developing thyroid cancer following exposure to radioactive iodine is very low for those aged 40 and over. Additionally, the risk of thyroid dysfunctions due to taking iodine tablets is higher. In particular, persons afflicted with goitre, thyroid gland nodules or hyperthyroidism have an increased risk of thyroid dysfunction and must consult with their general practitioner or their specialist before a state of emergency occurs.

10. SPECIAL WARNINGS AND USAGE PRECAUTIONS

If you suffer from one of the following rare conditions, it is recommended you consult with your doctor regarding the possible use of iodine tablets before a state of emergency occurs:

- Known hypersensitivity to iodine (very rare condition, not to be confused with the more common hypersensitivity to contrast dyes used during radiological procedures or in disinfectants)
- Dermatitis herpetiformis or Dühring disease (chronic skin condition)
- Hypocomplementaemic vasculitis (inflammation of the blood vessels)
- Iododerma Tuberosum (very rare skin condition characterised by the sudden appearance, after taking iodine, of little spots that strongly resemble acne, generally appearing on the face and limbs)
- Myotonia congenita (very rare condition accompanied by muscle stiffness)

11. ADVERSE EFFECTS

In rare cases, iodine tablets may change the way the thyroid works. However, this effect is negligible compared to the increased risk of thyroid cancer within the at-risk groups should the tablets not be taken.

These very rare cases most often occur in:

- Babies whose mother took iodine tablets while pregnant or breastfeeding
- Babies who have been given iodine tablets
- Those persons suffering or who have previously suffered from thyroid disease

If you or your child falls into one of these categories you should consult your doctor once the state of emergency has passed. Temporary stomach upsets may occur, especially when the tablets are taken without food or with an alcoholic drink. You should consult your doctor if symptoms persist.

If you or your child suffers problems with transpiration, heart palpitations, weight loss, fatigue or diarrhoea within a week to three months after taking iodine tablets, you should consult your doctor. In rare cases, the absorption of iodine may lead to hypersensitivity reactions such as skin redness (rash), a build-up of fluid (oedema), cervical pain, runny eyes, cold symptoms, swollen salivary glands and fever. These symptoms normally disappear without the need for treatment. In case of doubt, we recommend you consult your doctor.

Declaration of adverse affects

You can declare adverse effects directly at:

Federal agency for medicines and health products

Division Vigilance

EUROSTATION II

Place Victor Horta, 40/ 40

B-1060 BRUXELLES

Internet address: www.afmps.be

email: patientinfo@fagg-afmps.be

12. STORAGE AND STORAGE LENGTH

Store the iodine tablets at room temperature (between 15°C and 25°C), in a clean, dark place out of direct sunlight and out of reach of children.

The manufacturing date of the tablets appears on the packaging.

When stored in their original packaging as mentioned above, the iodine tablets are usable for at least 10 years. The tablets may turn a light yellowish-brown colour after a while, but this is harmless and does not affect their effectiveness.

Normally, the tablets should remain usable for period markedly greater than 10 years; the authorities verify the tablets regularly and, if necessary, you will be invited to replace them. Do not throw your old tablets away, simply return them to your pharmacist when you are invited to renew them.

13. ADDITIONAL INFORMATION

Additional information about this product can be found on the website <http://www.risquenucleaire.be>

14. URGENT REQUEST IN THE INTERESTS OF YOUR OWN SAFETY, ALWAYS FOLLOW THE INSTRUCTIONS GIVEN BY THE AUTHORITIES. THEY ARE BEST-PLACED TO ASSESS THE SITUATION.

This package leaflet was last updated in: 09/2017.