

Package leaflet: Information for the user

Jayempi 10 mg/ml oral suspension azathioprine

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Jayempi is and what it is used for

Jayempi 10 mg/ml oral suspension contains the active substance azathioprine. It belongs to a group of medicines called immunosuppressants.

These medicines reduce the activity of your immune system (the body's defences).

Jayempi is used to:

- Prevent your body from rejecting an organ transplant. Jayempi is usually used together with other immunosuppressants for this purpose
- Treat some long-term diseases where the immune system is reacting against your body. Jayempi is usually used in combination with steroids or other anti-inflammatory medicines. These diseases include:
 - Severe rheumatoid arthritis or chronic polyarthritis (long term chronic inflammation of multiple joints) which cannot be controlled by other medicines
 - Chronic inflammatory bowel diseases (diseases of the gut such as Crohn's disease and ulcerative colitis)
 - Chronic hepatitis (autoimmune hepatitis), a liver disease
 - Systemic lupus erythematosus (a disease in which the immune system attacks different organs)
 - Dermatomyositis (worsening muscle inflammation together with skin rash)
 - Polyarteritis nodosa (inflammation of blood vessels)
 - Pemphigus vulgaris and bullous pemphigoid (diseases of blistering of the skin)
 - Behçet's disease (recurrent inflammation, especially of the eyes and the oral and genital mucous membranes).
 - Refractory autoimmune haemolytic anaemia (a blood disease in which the red blood cells are destroyed)
 - Chronic refractory idiopathic thrombocytopenic purpura (bleeding under the skin due to damage to the platelets and reduction of their numbers)
- Treat relapsing multiple sclerosis.
- Treat generalised myasthenia gravis (a disease that affects nerves and causes muscle weakness). In some cases Jayempi is given in with a steroid at the start of treatment.

2. What you need to know before you take Jayempi

Do not take Jayempi

- if you are **allergic** to azathioprine, another medicine called mercaptopurine or any of the other ingredients of this medicine (listed in section 6).
- if you are breastfeeding.
- if you have recently had a vaccination with a live vaccine such as tuberculosis (BCG), chickenpox, MMR or yellow fever.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Jayempi:

- if you have a serious infection.
- if you have a serious liver disease.
- if you have a disease of the bone marrow or the pancreas.
- if you suffer from a condition known as Lesch-Nyhan syndrome (hereditary deficiency of the enzyme Hypoxanthine-guanine phosphoribosyl transferase).
- if you have a condition where your body produces too little of an enzyme called thiopurine methyltransferase (TPMT).
- if you take medicines like mesalazine, olsalazine or sulfasalazine (for the treatment of inflammatory bowel disease).
- if you take medicines which affect bone marrow function (for producing blood cells), such as penicillamine and cytotoxic medicines.

If you notice any unexplained bruising or bleeding during treatment or you have signs of infection, contact your doctor immediately.

Infections

Treatment with Jayempi increases the risk of infections and the infections may become more serious (see also section 4).

Because chickenpox (caused by varicella-zoster virus VZV) can be serious when you are taking Jayempi, you should avoid any contact with people suffering from chickenpox (varicella) or shingles (herpes zoster).

Tell your doctor if you come into contact with anyone who has chickenpox or shingles.

Your doctor will decide if you need antiviral treatment and if you should stop treatment with Jayempi.

Blood tests

You will need a blood test to check your blood cell count at least once a week during the first 8 weeks of treatment. You may need blood tests more often if you:

- are taking high doses of Jayempi
- are elderly
- have a kidney or liver disorder

After 8 weeks, your blood count should be checked once a month or at least every 3 months.

NUDT15-gene mutation

If you have an inherited mutation in the NUDT15-gene (a gene which is involved in the break-down of azathioprine in the body), you have a higher risk of infections and hair loss and your doctor may in this case give you a lower dose.

Your doctor may also ask you to have a test to check how well your body will be able to break-down this medicine. Your doctor may change your dose after these tests.

Taking Jayempi may increase your risk of:

- developing a serious condition called macrophage activation syndrome (excessive activation of white blood cells associated with inflammation), which usually occurs in people who have certain types of arthritis
- developing tumours, especially if you are receiving immunosuppressive therapy at high doses or for a long time
- developing cancers such as skin cancer caused by exposure to the sun. Therefore, you should avoid unnecessary exposure to the sunlight and UV light, wear protective clothing and use sunscreen (minimum of sun protection factor (SPF) 30)
- lymphoproliferative disorders (when the body produces white cells called lymphocytes in an uncontrolled way)
With treatments that include several immunosuppressants (including thiopurines like azathioprine) the condition can lead to death
- viral infections of the lymphatic system (Epstein-Barr virus related lymphoproliferative disorders), especially if several immunosuppressants are given at the same time.

This product may cause you to experience abnormally coloured urine, such as bright yellow urine. Although bright yellow urine is generally not concerning, you should discuss any change in the colour of your urine – including other discolourations or darkening – with your doctor, as this may indicate kidney or liver problems.

Other medicines and Jayempi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Jayempi can affect the way some medicines work. Also some other medicines can affect the way Jayempi works:

- **Ribavirin**, used to treat viral infections
- **Allopurinol, oxipurinol or thiopurinol** or other xanthine oxidase inhibitors, such as **febuxostat** (mainly used to treat gout)
- **Mesalazine, olsalazine, and sulfasalazine** (treatments for chronic inflammatory bowel disease such as Crohn's disease)
- **Anticoagulants** such as **warfarin**
- **ACE inhibitors** (such as enalapril, lisinopril, perindopril and ramipril, treatments for high blood pressure or heart failure)
- **Trimethoprim with sulfamethoxazole** (antibiotic)
- **Cimetidine** (treatment for ulcers of the digestive tract)
- **Indometacin** (treatment for rheumatoid arthritis)
- **Penicillamine** (mainly used in the treatment of rheumatoid arthritis)
- **Cytotoxic medicines** (to treat tumours, such as **methotrexate**)
- **Vaccination with live vaccines** during treatment with Jayempi can be harmful and must be avoided.
- **Atracurium** or **suxamethonium chloride** used as muscle relaxants in surgery.
- **Infliximab** (used for the treatment of inflammatory conditions such as rheumatoid arthritis, ulcerative colitis, Crohn's disease and psoriasis)

Before an operation tell your doctor that you are taking azathioprine because muscle relaxants used during anaesthesia may interact with azathioprine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Women taking Jayempi or the female partners of men taking Jayempi must not become pregnant during treatment and for 6 months afterwards. Both men and women taking Jayempi must use effective contraception during treatment with and for 6 months afterwards.

If you are planning to have a baby, talk to your doctor.

If you are pregnant, you should only take Jayempi if your doctor tells you to. **In case you are or believe you might be pregnant you must inform your doctor immediately.**

Changes in blood counts can occur in newborn babies of mothers who received azathioprine during pregnancy. Regular checks of blood counts during pregnancy are recommended.

Do not breast-feed during therapy with Jayempi. This is because small amounts may pass into the mother's milk.

Driving and using machines

Do not drive or use machines if you are affected or if you feel dizzy while taking this medicine.

Jayempi contains sodium benzoate (E211)

This medicine contains 1.5 mg sodium benzoate (E211) in each ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Jayempi contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Jayempi

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dose

The dose of Jayempi depends on your weight, the condition being treated, how well it is being controlled and your overall health. Your doctor will work out the dose that is right for you and may adjust it during treatment. The doctor will tell you how long you should continue taking the medicine.

For preventing organ rejection after transplantation, the usual starting dose is 5 mg per kg of your weight each day and the dose is then reduced after a few weeks or months to between 1 and 4 mg per kg of your weight each day.

The dose for other conditions is usually between 1 and 3 mg per kg of your weight each day.

Kidney/ liver disease

Your dose may be reduced if you have kidney or liver disease.

Use in children

The dose for children and adolescents is the same as the adult dose.

The safety and efficacy of azathioprine in children have not yet been established for the treatment of chronic joint inflammation (juvenile idiopathic arthritis) and multiple sclerosis. Therefore, the use of Jayempi for these conditions in children is not recommended.

Use in elderly patients

A reduced dose may be needed.

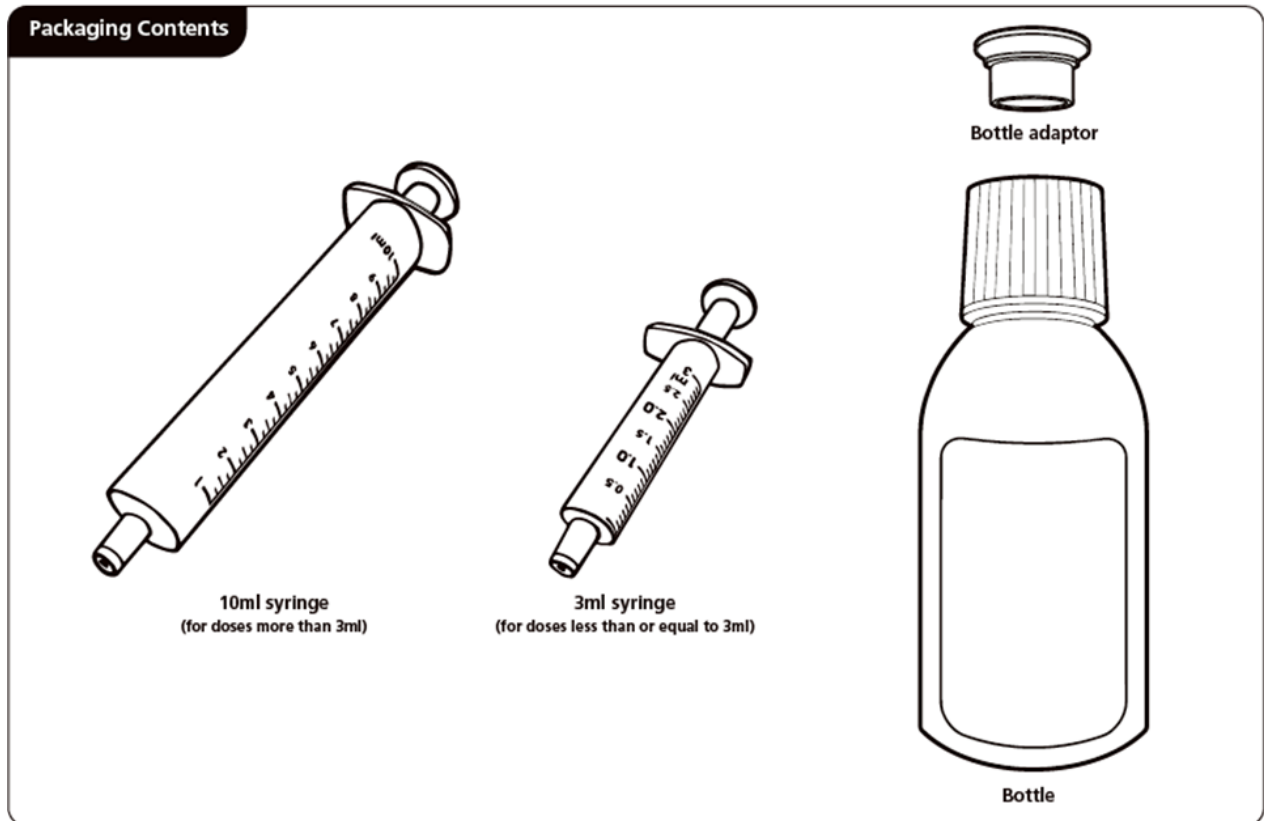
Jayempi with food and drink

Jayempi should be taken at least 1 hour before or 2 hours after a meal or milk. Check with your doctor or pharmacist if you are not sure.

You should drink some water after each dose of Jayempi. This helps to make sure that the full dose of the medicine enters your digestive system.

Handling

Your pack contains a 200-ml bottle of medicine, cap, a bottle adaptor and two dosing syringes (a 3-ml syringe and a 10-ml syringe). Always use the syringes provided to take your medicine.



- The **smaller** 3 ml oral syringe is marked from 0.5 ml to 3 ml with minor 0.1 ml graduations. It is used for measuring doses of up to 30 mg, in 1 mg (0.1 ml) step ups.
For example:
 - if the prescribed dose is 14 mg, use the 3 ml syringe and draw up a volume of 1.4 ml.
 - if the prescribed dose is 26 mg, use the 3 ml syringe and draw up a volume of 2.6 ml.
- The **larger** 10 ml oral syringe, is marked from 1 ml to 10 ml with minor 0.25 ml graduations. It is used for measuring doses greater than 30 mg, in 2.5 mg (0.25 ml) step ups.
For example:
 - if the prescribed dose is 32 mg, use the 10 ml syringe and draw up a volume of 3.25 ml.
 - if the prescribed dose is 54 mg, use the 10 ml syringe and draw up a volume of 5.5 ml.
 - if the prescribed dose is 140 mg, use the 10 ml syringe twice to draw up a dose of 10.0 ml followed by 4.0 ml (14 ml in total).

It is important to use the correct dosing syringe for your medicine. Your doctor or pharmacist will tell you which syringe to use depending on the dose prescribed for you.

If you are taking or giving the medicine to a child or somebody else, wash your hands before and after. Wipe up spillages immediately. To decrease the risk of coming into contact with the medicine, use disposable gloves when handling Jayempi.

If Jayempi comes into contact with skin, eyes or nose, wash the area immediately and thoroughly with soap and water.

When you use the medicine follow the instructions below:

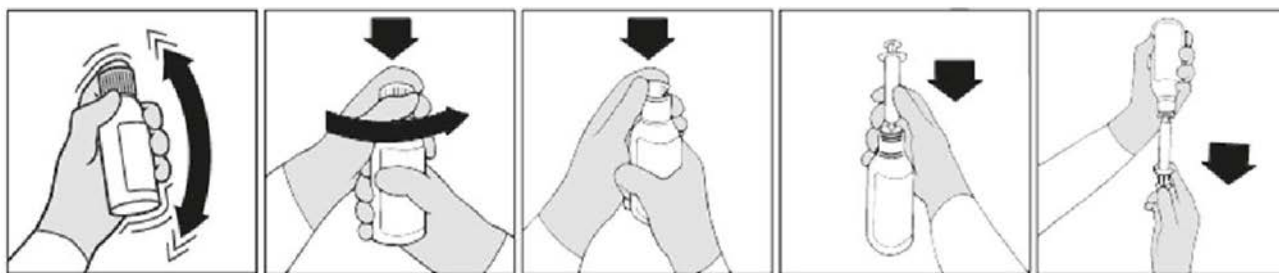


Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

1. Put on disposable hand gloves before handling Jayempi.
2. Shake the bottle to mix the medicine well (**figure 1**).
3. Remove the bottle cap (**figure 2**) and push the adaptor firmly into the top of the bottle and leave in place for future doses (**figure 3**).
4. Push the tip of the dosing syringe into the hole in the adaptor (**figure 4**). Your doctor or pharmacist will tell you which is the correct syringe to use.
5. Turn the bottle upside down (**figure 5**).
6. Pull the plunger of the syringe back so that the medicine is drawn from the bottle into the syringe. Pull the plunger back to the point on the scale that corresponds to the dose prescribed (figure 5). If you are not sure about how much medicine to draw into the syringe, always ask your doctor or nurse for advice.
7. Turn the bottle back the right way up and carefully remove the syringe from the adaptor, holding it by the barrel rather than the plunger.
8. Gently put the tip of the syringe into your mouth and to the inside of your cheek.
9. Slowly and gently push the plunger down to gently squirt the medicine into the inside of your cheek and swallow it. DO NOT forcefully push down the plunger, or squirt the medicine to the back of your mouth or throat, as you may choke.
10. Remove the syringe from your mouth.
11. Swallow the dose of oral suspension then drink some water, making sure no medicine is left in your mouth.
12. Put the cap back on the bottle with the adaptor left in place. Ensure that the cap is tightly closed.
13. Wash the syringe with cold or warm tap water and rinse well. Hold the syringe under water and move the plunger up and down several times to make sure the inside of the syringe is clean. Let the syringe dry completely before you use it again for the next dose. Store the syringe in a clean place, with the medicine.

Repeat the above for each dose as instructed by your doctor or pharmacist.

If you take more Jayempi than you should

If you take more Jayempi than you should, talk to your doctor or go to a hospital immediately. Take the medicine pack with you.

The most likely effect of an overdose is bone marrow suppression reaching its maximum 9-14 days after dosing.

Bone marrow suppression reduces your blood counts and in severe cases lead to dangerous infections and other serious effects. Some symptoms of bone marrow suppression include feeling tired, ulcers in the mouth and throat, fever and infection, and unexplained bruising and bleeding.

If you forget to take Jayempi

Do not take a double dose to make up for a forgotten dose. Take the next dose as usual.

If you have forgotten more than one dose, speak with your doctor.

If you stop taking Jayempi

Treatment with Jayempi should always be under close medical supervision. Talk to your doctor, if you

wish to interrupt or stop the treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

If you get any of the following serious side effects, stop taking Jayempi and talk to your doctor or go to hospital immediately:

- Allergic reaction, the signs may include:
general tiredness, dizziness, feeling sick (nausea), being sick (vomiting) or diarrhoea, high temperature (fever), shivering or chills, redness of the skin, skin nodules, or a skin rash, pain in the muscles or joints, changes in the colour of your urine (kidney problems), confusion, feeling light headed or weak (caused by low blood pressure).

If you get any of the following serious side effects, talk to your doctor or go to hospital immediately:

- fever or you notice any signs of infection, such as headache and body aches, coughing or difficulty breathing (similar to a chest infection)
- if you come into contact with anyone who is suffering from chickenpox or shingles
- you notice any of the following: black (tar) stool, blood in the stool, abdominal pain or yellowing of the skin and the white of the eye
- you bruise easily or notice any unusual bleeding
- you feel extremely tired
- you notice lumps anywhere on your body
- you notice any changes to your skin, for example blisters or peeling
- your health suddenly gets worse

Other side effects include:

Very common (may affect more than 1 in 10 people)

- Reduction in your bone marrow function, which may make you feel unwell or show up in your blood tests
Suppression of bone marrow function generally returns to normal when the dose is adjusted.
Signs of abnormal bone marrow function may be: increased susceptibility to infections, ulcers in the mouth and throat, increased bleeding, fatigue and poor mental and physical performance
- Low white blood cell level in your blood tests (leucopenia), which may cause infection
- Infections in transplant recipients who take Jayempi in combination with other immunosuppressants

Common (may affect up to 1 in 10 people)

- Low blood platelet level (thrombocytopenia), which may cause you to bruise or bleed easily
- Nausea, occasionally combined with vomiting

Uncommon (may affect up to 1 in 100 people)

- Low red blood cell level (anaemia), which may cause you to be tired, get headaches, be short of breath when exercising, feel dizzy and look pale
- Inflammation of the pancreas, especially in transplant recipients and in patients with inflammatory bowel disease
- Infections in patients who have not received other immunosuppressants in combination with

- their azathioprine
- Hypersensitivity reactions. In very rare cases, fatal hypersensitivity reactions have occurred
- Liver problems, which may cause pale stools, dark urine, itchiness and yellowing of your skin and eyes
- Bile congestion
- Worsening of liver function values

Liver damage and bile congestion are dose-dependent and they are usually decreased after the discontinuation of treatment.

Rare (may affect up to 1 in 1,000 people)

- Various types of cancer, including blood, lymph and skin cancer (malignant blood system disorders such as acute myeloid leukaemias and myelodysplasias, which are typical of immune system suppression)
- Bone marrow failure resulting in reduction of the number of certain white or red blood cells (agranulocytosis, aplastic anaemia), of all blood cells (pancytopenia), increased occurrence of abnormal, unusually large immature red blood cells (megaloblastic anaemia) and of small red blood cells in the blood
Although changes in the blood count usually occur at the start of therapy, they can also occur later, during the therapy. Therefore, a regular check of blood cell count is advised even for patients who remain stable, during long-term treatment
- Severe liver damage which can be life threatening, especially in transplant patients who receive long treatment
In some cases, discontinuing treatment with Jayempi, may improve the symptoms
- Hair loss. In many cases, it may get better even though you continue to take azathioprine. The relation between hair loss and the use of azathioprine is not clear

Very rare (may affect up to 1 in 10,000 people)

- Anaemia due to increased red blood cell break down (haemolytic anaemia)
- Severe skin reactions with blistering and detachment of the skin, especially on the extremities, in the mouth, eyes and genital area, associated with poor general condition and fever (Stevens-Johnson syndrome, toxic epidermal necrolysis)
A variety of reactions of possibly allergic origin have been reported. Signs of such hypersensitivity reactions can be feeling unwell, dizziness, drowsiness, nausea (feeling sick), vomiting, diarrhoea, fever, chills, skin rash, vascular inflammation, muscle and joint pain, drop in blood pressure, kidney and liver problems and blockage of the bile duct (biliary obstruction). In very rare cases, fatal hypersensitivity reactions have been reported
- Pneumonia gets better after stopping treatment with Jayempi
- Severe inflammatory diseases of the colon (colitis, diverticulitis) and bowel perforation in transplant recipients
- Severe diarrhoea in patients with inflammatory bowel disease
- Gastrointestinal disturbance leading to diarrhoea, abdominal (belly) pain, constipation, nausea and vomiting
- A certain type of lymphoma (hepatosplenic T-cell lymphoma)
- A disease of the white matter of the brain (PML), caused by the JC virus

If you suffer from nausea with occasional vomiting, your doctor may ask you to take Jayempi after a meal to reduce these symptoms. Tell your doctor if you have severe diarrhoea or nausea and vomiting'

Not known (frequency cannot be derived from the available data)

- You may develop a rash (raised red, pink or purple lumps which are sore to touch), particularly on your arms, hands, fingers, face and neck, which may also be accompanied by fever (Sweet's syndrome, also known as acute febrile neutrophilic dermatosis).

- Sensitivity to sunlight which can cause skin discoloration or a rash.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Jayempi

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month.
- After first opening of the bottle, discard any unused contents after 12 weeks.
- Do not store above 25°C.
- Keep the bottle tightly closed to prevent spoilage of the medicine and reduce the risk of accidental spillage.

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 Jayempi contains

The active substance is azathioprine. One ml of suspension contains 10 mg azathioprine.

The other ingredients are sodium benzoate (E211), sucralose (E955), banana flavour, citric acid monohydrate, microcrystalline cellulose and carmellose sodium, xanthan gum and purified water. See section 2 “Jayempi contains sodium benzoate” and “Jayempi contains sodium”.

What Jayempi looks like and contents of the pack

Jayempi is a yellow, viscous oral suspension. It comes in glass bottles of 200 ml capped with a child-resistant closure. Each pack contains one bottle, a bottle adaptor and two dosing syringes (a syringe graduated to 3 ml and a syringe graduated to 10 ml).

Your doctor or pharmacist will advise which syringe to use depending on the dose that has been prescribed.

Marketing Authorisation Holder

Nova Laboratories Limited
Martin House, Gloucester Crescent
Wigston, Leicester
LE18 4YL
United Kingdom

Manufacturer

Nova Laboratories Limited
Martin House, Gloucester Crescent
Wigston, Leicester
LE18 4YL

United Kingdom

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The following information is intended for healthcare professionals only:

To measure the dose in ml in accordance with the prescribed posology, two oral syringes are included in the pack; 3 ml and 10 ml. The oral syringes are graduated in 0.1 ml (1 mg) and 0.25 ml (2.5 mg) steps respectively.

The table below shows, for a range of age, weight and doses, the dose (mg) to volume (ml) conversion using the two oral syringes.

Table 1: Dose (mg) to volume (ml) conversion using the two oral syringes

Age (Years)	Weight* (Kg)	Dose†									
		1mg/kg		2mg/kg		3mg/kg		4mg/kg		5mg/kg	
		mg	ml	mg	ml	mg	ml	mg	ml	mg	ml
0	3.3	3.3	0.3	6.6	0.7	9.9	1.0	13.2	1.3	16.5	1.7
1 month	4.5	4.5	0.5	9.0	0.9	13.5	1.4	18.0	1.8	22.5	2.3
2 month	5.6	5.6	0.6	11.2	1.1	16.8	1.7	22.4	2.2	28.0	2.8
3 month	6.4	6.4	0.6	12.8	1.3	19.2	1.9	25.6	2.6	32.0	3.25
4 month	7.0	7.0	0.7	14.0	1.4	21.0	2.1	28.0	2.8	35.0	3.50
5 month	7.5	7.5	0.8	15.0	1.5	22.5	2.3	30.0	3.0	37.5	3.75
6 month	7.9	7.9	0.8	15.8	1.6	23.7	2.4	31.6	3.25	39.5	4.00
1.0	9.6	9.6	1.0	19.2	1.9	28.8	2.9	38.4	3.75	48.0	4.75
1.5	10.9	10.9	1.1	21.8	2.2	32.7	3.25	43.6	4.25	54.5	5.50
2.0	12.2	12.2	1.2	24.4	2.4	36.6	3.75	48.8	5.00	61.0	6.00
3.0	14.3	14.3	1.4	28.6	2.9	42.9	4.25	57.2	5.75	71.5	7.25
4.0	16.3	16.3	1.6	32.6	3.25	48.9	5.00	65.2	6.50	81.5	8.25
5.0	18.3	18.3	1.8	36.6	3.75	54.9	5.50	73.2	7.25	91.5	9.25
6.0	20.5	20.5	2.1	41.0	4.00	61.5	6.25	82.0	8.25	102.5	10.25
7.0	22.9	22.9	2.3	45.8	4.50	68.7	7.00	91.6	9.25	114.5	11.50
8.0	25.4	25.4	2.5	50.8	5.00	76.2	7.50	101.6	10.25	127.0	12.75
9.0	28.1	28.1	2.8	56.2	5.50	84.3	8.50	112.4	11.25	140.5	14.00
10.0	31.2	31.2	3.0	62.4	6.25	93.6	9.25	124.8	12.50	156.0	15.50
12.0	38.2	38.2	3.75	76.4	7.75	114.6	11.50	152.8	15.25	191.0	19.00
15.0	55.5	55.5	5.50	111.0	11.00	166.5	16.75	222.0	22.25	277.5	27.75
18.0	67.0	67.0	6.75	134.0	13.50	201.0	20.00	268.0	26.75	335.0	33.50

*50th percentile for boys extracted from WHO (0-10 years) and UK (11-18 years) growth charts

†Doses less than or equal to 30 mg to be drawn up using the 3 ml oral syringe with 0.1 ml graduations. Doses greater than 30 mg to be drawn up using the 10 ml oral syringe with 0.25 ml graduations (shaded cells).

The healthcare professional should advise the patient or carer which syringe to use to ensure that the correct volume is administered.