

Package leaflet: Information for the patient

Triumeq 5 mg/60 mg/30 mg dispersible tablets dolutegravir/abacavir/lamivudine

Read all of this leaflet carefully before you start using 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 or pharmacist.
- This medicine has been prescribed for a child in your care. Do not pass it on to others. It may harm them, even if their signs of illness are the same as those of the child you are caring for.
- If the child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Triumeq is and what it is used for
2. What you need to know before you use Triumeq
3. How to take Triumeq
4. Possible side effects
5. How to store Triumeq
6. Contents of the pack and other information
7. Step-by-step instructions for use

1. What Triumeq is and what it is used for

Triumeq is a medicine that contains three active substances used to treat HIV infection: abacavir, lamivudine and dolutegravir. Abacavir and lamivudine belong to a group of anti-retroviral medicines (medicines used to treat HIV infection) called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*, and dolutegravir belongs to a group of anti-retroviral medicines called *integrase inhibitors (INIs)*.

Triumeq is used to treat **HIV (human immunodeficiency virus) infection** in children who weigh at least 14 kg and less than 25 kg.

Before the child you are caring for is prescribed Triumeq your doctor will arrange a test to find out whether they carry a particular type of gene called HLA-B*5701. Triumeq should not be used in patients who are known to carry the HLA-B*5701 gene. Patients with this gene are at a high risk of developing a serious hypersensitivity (allergic) reaction if they use Triumeq (see 'hypersensitivity reactions' in section 4).

Triumeq does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. It also increases the number of CD4 cells in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Not everyone responds to treatment with Triumeq in the same way. Your doctor will monitor the effectiveness of the child's treatment.

2. What you need to know before you use Triumeq

Do not use Triumeq

- if the child you are caring for is **allergic** (*hypersensitive*) to dolutegravir, abacavir (or any other medicine containing abacavir), or lamivudine, or any of the other ingredients of this medicine (listed in section 6).

Carefully read all the information about hypersensitivity reactions in Section 4.

- If the child you are caring for is taking a medicine called **fampridine** (also known as dalfampridine; used in multiple sclerosis).
- If you think any of these apply to the child, tell your doctor.

Warnings and precautions

IMPORTANT — Hypersensitivity reactions

Triumeq contains abacavir and dolutegravir. Both of these active substances can cause a serious allergic reaction known as a hypersensitivity reaction. The child you are caring for should never take abacavir or abacavir-containing products again if they have a hypersensitivity reaction: it can be life threatening.

You must carefully read all the information under ‘Hypersensitivity reactions’ in the panel in Section 4.

The Triumeq pack includes an **Alert Card** to remind you and medical staff about hypersensitivity.

Detach this card and keep it with you at all times.

Take special care with Triumeq

Some people taking Triumeq or other combination treatments for HIV are more at risk of serious side effects than others. You need to be aware of the extra risks:

- if the child you are caring for has moderate or severe liver disease
- if the child you are caring for has ever had **liver disease**, including hepatitis B or C (if the child has hepatitis B infection, don't stop Triumeq without your doctor's advice, as their hepatitis may come back)
- if the child you are caring for has a kidney problem
→ **Talk to your doctor if any of these apply to the child before using Triumeq.** They may need extra check-ups, including blood tests, while they are taking the medicine. See Section 4 for more information.

Abacavir hypersensitivity reactions

Even patients who don't have the HLA-B*5701 gene may still develop a **hypersensitivity reaction** (a serious allergic reaction).

→ **Carefully read all the information about hypersensitivity reactions in Section 4 of this leaflet.**

Risk of cardiovascular events

It cannot be excluded that abacavir may increase the risk of having cardiovascular events.

→ **Tell your doctor** if the child you are caring for has cardiovascular problems, if they smoke, or have other illnesses that may increase their risk of cardiovascular diseases such as high blood pressure or diabetes. Don't stop giving Triumeq unless your doctor advises you to do so.

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious.

These include:

- symptoms of infections and inflammation
- joint pain, stiffness and bone problems

You need to know about important signs and symptoms to look out for while you're giving Triumeq.

→ **Read the information ‘Other possible side effects of combination therapy for HIV’ in Section 4 of this leaflet.**

Children

This medicine is not for children weighing less than 14 kg because the dose of each component of this medicine cannot be adjusted to their weight.

Children must **keep planned doctor’s appointments** (*see Section 3, How to give Triumeq, for more information*).

Other medicines and Triumeq

Tell your doctor if the child you are caring for is taking, has recently taken or might take any other medicines.

Some medicines can affect how Triumeq works, or make it more likely that you will have side effects. Triumeq can also affect how some other medicines work.

Tell your doctor if you are taking any of the medicines *in the following list*:

- metformin, to treat **diabetes**
- medicines called **antacids**, to treat **indigestion** and **heartburn**. **Do not take an antacid** during the 6 hours before you take Triumeq, or for at least 2 hours after you take it. (*See also Section 3*).
- supplements or multivitamins containing calcium, iron or magnesium. **If you take Triumeq with food**, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as Triumeq. **If you do not take Triumeq with food, do not take supplements or multivitamins containing calcium, iron or magnesium** during the 6 hours before you take Triumeq, or for at least 2 hours after you take it (*see also Section 3*).
- emtricitabine, etravirine, efavirenz, nevirapine or tipranavir/ritonavir, to treat **HIV infection**
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly
- other medicines containing lamivudine, used to treat **HIV infection** or **hepatitis B infection**
- cladribine, used to treat **hairy cell leukaemia**
- rifampicin, to treat tuberculosis (TB) and other **bacterial infections**
- trimethoprim/sulfamethoxazole, an antibiotic to treat **bacterial infections**
- phenytoin and phenobarbital, to treat **epilepsy**
- oxcarbazepine and carbamazepine, to treat **epilepsy** and **bipolar disorder**
- **St. John’s wort** (*Hypericum perforatum*), a herbal remedy to treat **depression**
- **methadone**, used as a **heroin substitute**. Abacavir increases the rate at which methadone is removed from the body. If you are taking methadone, you will be checked for any withdrawal symptoms. Your methadone dose may need to be changed

→ **Tell your doctor or pharmacist** if the child you are caring for is taking any of these. Your doctor may decide to adjust the child’s dose or that the child needs extra checkups.

Pregnancy

Patients who are pregnant, think they may be pregnant, or are planning to have a baby:

→ **Talk to your doctor** about the risks and benefits of taking Triumeq.

Taking Triumeq at the time of becoming pregnant or during the first six weeks of pregnancy, may increase the risk of a type of birth defect, called neural tube defect, such as spina bifida (malformed spinal cord).

Patients who could get pregnant while receiving Triumeq:

→ **Talk to your doctor** and discuss whether there is a need for contraception, such as condom or pills.

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor will review your treatment. Do not stop taking Triumeq without consulting your doctor, as this may harm you and your unborn child.

Breast-feeding

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredients in Triumeq can also pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding **you should discuss it with your doctor as soon as possible.**

Driving and using machines

Triumeq can make you dizzy and have other side effects that make you less alert.

→ **Don't drive or operate machinery** unless you are sure your alertness has not been affected.

Triumeq contains sodium

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

3. How to give Triumeq

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

Your doctor will decide on the correct dose of Triumeq for the child you are caring for, depending on the weight of the child.

If the child you are caring for weighs less than 14 kg, Triumeq is not suitable for the child, because it is not known if Triumeq is safe and effective. Your doctor should prescribe the components separately for the child.

Triumeq can be given **with or without food.**

The dispersible tablets must be dispersed in drinking water. The tablets should be fully dispersed before swallowing. Do not chew, cut or crush the tablets.

Children's dose of Triumeq needs to be adjusted as they gain weight.

→ It is important therefore that children **keep planned doctor's appointments.**

Triumeq is available as film-coated and dispersible tablets. Film-coated tablets and dispersible tablets are not the same. Therefore, you should not switch between film-coated tablets and dispersible tablets without first talking to your doctor.

Do not give an antacid during the 6 hours before you give Triumeq, or for at least 2 hours after you give it. Other acid-lowering medicines like ranitidine and omeprazole can be taken at the same time as Triumeq.

→ Talk to your doctor for further advice on taking antacid medicines with Triumeq.

If you give Triumeq with food, you can give supplements or multivitamins containing calcium, iron or magnesium at the same time as Triumeq. **If you do not give Triumeq with food**, do not give a supplement or multivitamin containing calcium, iron or magnesium during the 6 hours before you give Triumeq, or for at least 2 hours after you give it.

→Talk to your doctor for further advice on taking supplements or multivitamins containing calcium, iron or magnesium with Triumeq.

If you give more Triumeq than you should

If you give too many dispersible tablets of Triumeq, **contact your doctor or pharmacist for advice**. If possible, show them the Triumeq pack.

If you forget to give Triumeq

If you miss a dose, give it as soon as you remember. But if the next dose is due within 4 hours, skip the dose you missed and give the next one at the usual time. Then continue the child's treatment as before.

→ **Don't give a double dose** to make up for a missed dose.

If you have stopped giving Triumeq

If you have stopped giving Triumeq to the child for any reason — especially because you think they are having side effects, or because they have another illness:

Talk to your doctor before you start giving it again. Your doctor will check whether the child's symptoms were related to a hypersensitivity reaction. If the doctor thinks they may be related to a hypersensitivity reaction, **you will be told never again to give Triumeq, or any other medicine containing abacavir or dolutegravir.** It is important that you follow this advice.

If your doctor advises that you can start giving Triumeq again, you may be asked to give the first doses in a place where the child will have ready access to medical care if they need it.

4. Possible side effects

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

When the child is being treated for HIV, it can be hard to tell whether a symptom is a side effect of Triumeq or other medicines they are taking, or an effect of the HIV disease itself. **So it is very important to talk to your doctor about any changes in the child's health.**

Abacavir can cause a hypersensitivity reaction (a serious allergic reaction), especially in people who carry a particular type of gene called HLA-B*5701. Even patients who don't have the HLA-B*5701 gene may still develop **a hypersensitivity reaction**, described in this leaflet in the panel headed 'Hypersensitivity reactions'. **It is very important that you read and understand the information about this serious reaction.**

As well as the side effects listed below for Triumeq, other conditions can develop during combination therapy for HIV.

It is important to read the information in this section under the heading 'Other possible side effects of combination therapy for HIV'.

Hypersensitivity reactions

Triumeq contains abacavir and dolutegravir. Both of these active substances can cause a serious allergic reaction known as a hypersensitivity reaction.

These hypersensitivity reactions have been seen more frequently in people taking medicines that contain abacavir.

Who gets these reactions?

Anyone taking Triumeq could develop a hypersensitivity reaction, which could be life threatening if they continue to take Triumeq.

The child is more likely to develop this reaction if they have a gene called HLA-B*5701 (but they can get a reaction even if they don't have this gene). The child you are caring for should have been tested for this gene before Triumeq was prescribed for them. If you know they have this gene, tell your doctor.

What are the symptoms?

The most common symptoms are:

fever (high temperature) and **skin rash**.

Other common symptoms are:

nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain, severe tiredness.

Other symptoms include:

pains in the joints or muscles, swelling of the neck, shortness of breath, sore throat, cough, occasional headaches, inflammation of the eye (conjunctivitis), mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.

When do these reactions happen?

Hypersensitivity reactions can start at any time during treatment with Triumeq, but are more likely during the first 6 weeks of treatment.

Contact your doctor immediately:

- 1 if the child gets a skin rash, OR**
- 2 if the child gets symptoms from at least 2 of the following groups:**
 - fever
 - shortness of breath, sore throat or cough
 - nausea or vomiting, diarrhoea or abdominal pain
 - severe tiredness or aches and pains, or generally feeling ill.

Your doctor may advise you to stop giving Triumeq.

If you have stopped giving Triumeq

If you have stopped giving Triumeq to the child because of a hypersensitivity reaction, **they must NEVER AGAIN take Triumeq, or any other medicine containing abacavir.** If they do, within

hours, their blood pressure could fall dangerously low, which could result in death. They should also never again take medicines containing dolutegravir.

If the child has stopped taking Triumeq for any reason — especially because you think they are having side effects, or because they have other illness:

Talk to your doctor before you start again. Your doctor will check whether the child's symptoms were related to a hypersensitivity reaction. If the doctor thinks they may have been, **you will then be told never again to give Triumeq, or any other medicine containing abacavir.** You may also be told never again to give any other medicine containing dolutegravir. It is important that you follow this advice.

Occasionally, hypersensitivity reactions have developed in people who start taking abacavir containing products again, but who had only one symptom on the Alert Card before they stopped taking it.

Very rarely, patients who have taken medicines containing abacavir in the past without any symptoms of hypersensitivity have developed a hypersensitivity reaction when they start taking these medicines again.

If your doctor advises that you can start giving Triumeq again, you may be asked to give the first doses in a place where the child will have ready access to medical care if you need it.

If the child is hypersensitive to Triumeq, return all the unused Triumeq tablets for safe disposal. Ask your doctor or pharmacist for advice.

The Triumeq pack includes an **Alert Card**, to remind you and medical staff about hypersensitivity reactions. **Detach this card and keep it with you at all times.**

Very common side effects

These may affect **more than 1 in 10 people**:

- headache
- diarrhoea
- feeling sick (*nausea*)
- difficulty in sleeping (*insomnia*)
- lack of energy (*fatigue*)

Common side effects

These may affect **up to 1 in 10 people**:

- hypersensitivity reaction (*see 'Hypersensitivity reactions' earlier in this section*)
- loss of appetite
- rash
- itching (*pruritus*)
- being sick (*vomiting*)
- stomach (*abdominal*) pain
- stomach (*abdominal*) discomfort
- weight gain
- indigestion
- wind (*flatulence*)
- dizziness
- abnormal dreams
- nightmares
- depression (feelings of deep sadness and unworthiness)

- anxiety
- tiredness
- feeling drowsy
- fever (*high temperature*)
- cough
- irritated or runny nose
- hair loss
- muscle pain and discomfort
- joint pain
- feeling weak
- general feeling of being unwell

Common side effects that may show up in blood tests are:

- an increase in the level of liver enzymes

Uncommon side effects

These may affect **up to 1 in 100 people**:

- inflammation of the liver (*hepatitis*)
- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)
- panic attack

Uncommon side effects that may show up in blood tests are:

- a decreased number of cells involved in blood clotting (*thrombocytopenia*).
- a low red blood cell count (*anaemia*) or low white blood cell count (*neutropenia*)
- an increase in sugar (glucose) in the blood
- an increase in triglycerides (type of fat) in the blood

Rare side effects

These may affect **up to 1 in 1000 people**:

- inflammation of the pancreas (*pancreatitis*)
- breakdown of muscle tissue
- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine).
- suicide (particularly in patients who have had depression or mental health problems before)

→ **Tell your doctor immediately** if you experience any mental health problems (see also other mental health problems above).

Rare side effects that may show up in blood tests are:

- increase in bilirubin (a test of liver function)
- increase in an enzyme called *amylase*.

Very rare side effects

These may affect **up to 1 in 10,000 people**:

- numbness, tingly feelings in the skin (pins and needles)
- sensation of weakness in the limbs
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens–Johnson syndrome*), and a more severe form causing skin peeling in more than 30% of the body surface (*toxic epidermal necrolysis*)
- lactic acidosis (excess lactic acid in the blood).

Very rare side effects that may show up in blood tests are:

- a failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

If the child you are caring for gets any side effects

→ **Talk to your doctor**. This includes any possible side effects not listed in this leaflet.

Other possible side effects of combination therapy for HIV

Combination therapy such as Triumeq may cause other conditions to develop during HIV treatment.

Symptoms of infection and inflammation

People with advanced HIV infection or AIDS have weak immune systems, and are more likely to develop serious infections (*opportunistic infections*). Such infections may have been “silent” and not detected by the weak immune system before treatment was started. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. Symptoms usually include **fever**, plus some of the following:

- headache
- stomach ache
- difficulty breathing

In rare cases, as the immune system becomes stronger, it can also attack healthy body tissue (*autoimmune disorders*). The symptoms of autoimmune disorders may develop many months after the child starts taking medicine to treat their HIV infection. Symptoms may include:

- palpitations (rapid or irregular heartbeat) or tremor
- hyperactivity (excessive restlessness and movement)
- weakness beginning in the hands and feet and moving up towards the trunk of the body.

If the child gets any symptoms of infection and inflammation or if you notice any of the symptoms above:

→ **Tell your doctor immediately**. Don't give other medicines for the infection without your doctor's advice.

Joint pain, stiffness and bone problems

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. In this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:

→ **Tell your doctor.**

Weight, blood lipid and blood glucose effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and lifestyle, and sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Reporting of side effects

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

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 bottle label after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant. Do not swallow the desiccant.

This medicine does not require any special temperature storage conditions.

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 Triumeq contains**

- The active substances are dolutegravir, abacavir and lamivudine. Each tablet contains dolutegravir sodium equivalent to 5 mg dolutegravir, 60 mg abacavir (as sulfate) and 30 mg lamivudine.
- The other ingredients are acesulfame potassium, crospovidone, mannitol (E421), microcrystalline cellulose, povidone, silicified microcrystalline cellulose (cellulose, microcrystalline; silica, colloidal anhydrous), sodium starch glycolate, sodium stearyl fumarate, strawberry cream flavour, sucralose, polyvinyl alcohol-part hydrolyzed, macrogol, talc, titanium dioxide (E171) and iron oxide yellow (E172).
- This medicine contains less than 1 mmol sodium (23 mg) per dispersible tablet, that is to say essentially 'sodium-free'.

What Triumeq looks like and contents of the pack

Triumeq dispersible tablets are yellow, biconvex, capsule shaped tablets, debossed with "SV WTU" on one side.

The dispersible tablets are provided in bottles containing 90 tablets.

The bottle contains a desiccant to reduce moisture. Once the bottle has been opened keep the desiccant in the bottle, do not remove it.
A dosing cup is supplied with the pack

Marketing Authorisation Holder

ViiV Healthcare UK Limited
980 Great West Road
Brentford
Middlesex
TW8 9GS
United Kingdom

Manufacturer

Glaxo Operations UK Ltd (trading as Glaxo Wellcome Operations), Priory Street, Ware,
Hertfordshire SG12 0DJ, UK

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Triumeq
Reference number	35728/0060

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in November 2023.

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7. Step-by-step instructions

Read the Instructions for Use before giving a dose of medicine.
Follow the steps, using clean drinking water to prepare and give a dose to a child.

Important information

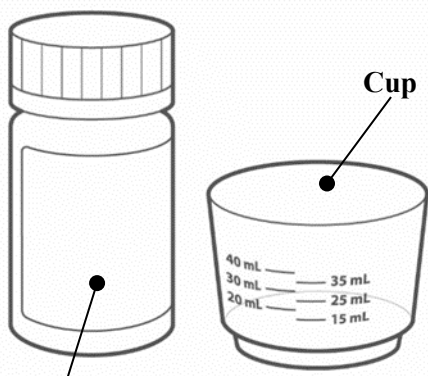
Always give this medicine exactly as your healthcare provider tells you. Talk to your healthcare provider if you are not sure.

Do not chew, cut, or crush the tablets.

If you forget to give a dose of medicine, give it as soon as you remember. But if your next dose is due within 4 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before. Do not give 2 doses at the same time or give more than your healthcare provider has prescribed.

If your child does not or cannot take the full dose call your healthcare provider.

If you give too much medicine, get emergency medical help right away.



Bottle

Your pack contains:

- A bottle containing 90 tablets.
- Dosing cup.

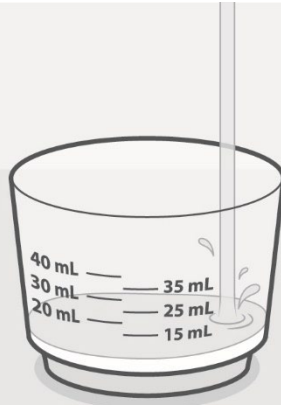
You will also need:

- Clean drinking water.

Getting ready

1. Pour water

Water Volume Guide	
Number of tablets	Volume of water
5	20 mL
6	20 mL

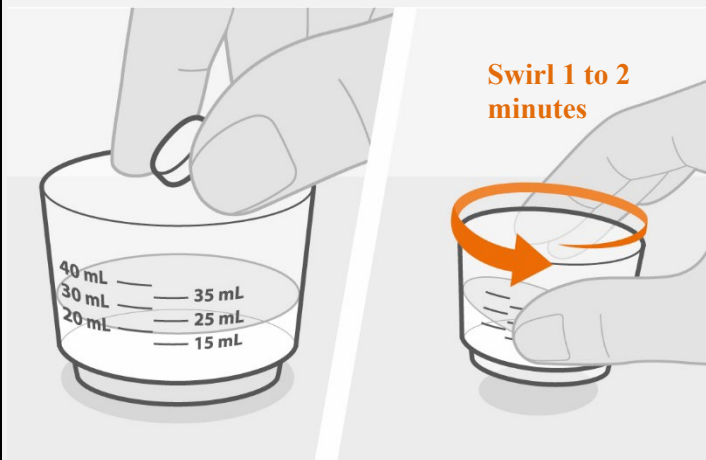


- Pour clean drinking water into the cup.
The Water Volume Guide above shows the amount of water needed for the prescribed dose.

Use drinking water only.

- **Do not** use any other drink or food to prepare the dose

2. Prepare the medicine



- Add the prescribed number of tablet(s) to the water.
- Swirl the cup gently for 1 to 2 minutes to disperse the tablet(s). The medicine will become cloudy. Take care not to spill any of the medicine.
- Check that the medicine is ready. If there are any lumps of tablet swirl the cup until they have gone.

If you spill any medicine, clean up the spill.

Throw away the rest of the prepared medicine and make a new dose.

You must give the dose of medicine within 30 minutes of preparing the dose. If it has been more than 30 minutes wash away all the dose in the cup using water and prepare a new dose of medicine.

Giving the medicine

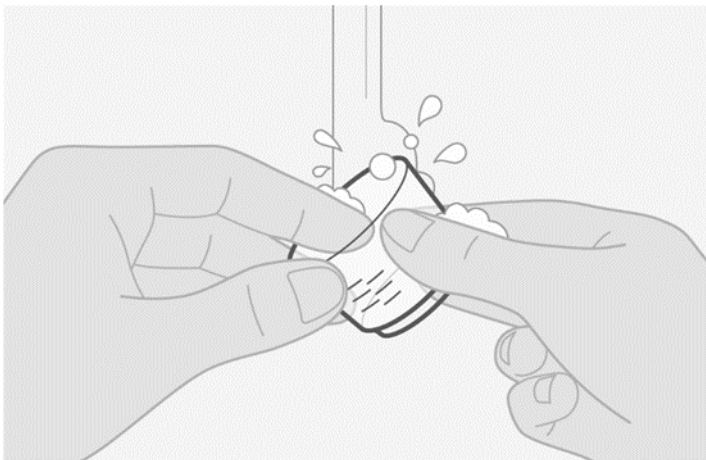
3. Give the medicine



- Make sure that the child is upright. Give all the prepared medicine to the child.
- Add another 15 mL or less of drinking water to the cup, swirl and give it all to the child.
- **Repeat if any medicine remains to make sure the child gets the full dose.**

Cleaning

4. Clean the dosing items



- Wash the cup with water.
- The cup will need to be cleaned before preparing the next dose.

Storage information

Keep the tablets in the bottle. Keep the bottle tightly closed.

The bottle contains a desiccant canister which helps to keep the tablets dry. **Do not** eat the desiccant. **Do not** remove the desiccant.

Keep all medicines out of reach of children.

Disposal information

When all the tablets in the bottle have been taken or are no longer needed, throw away the bottle and cup. Dispose of them using your local household waste guidelines.

You will get a new cup in your next pack.