Package leaflet: Information for the patient
XELJANZ® 1 mg/mL oral solution
tofacitinib

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In addition to this leaflet, your doctor will also give you a Patient Alert Card, which contains important safety information that you need to be aware of before you are given XELJANZ and during treatment with XELJANZ. Keep this Patient Alert Card with you.

What is in this leaflet

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

1. What XELJANZ is and what it is used for

XELJANZ 1 mg/mL oral solution is a medicine that contains the active substance tofacitinib.

XELJANZ 1 mg/mL oral solution is used for the treatment of active polyarticular juvenile idiopathic arthritis, a long-term disease that mainly causes pain and swelling of your joints, in patients 2 years of age and older.

XELJANZ 1 mg/mL oral solution is also used for the treatment of juvenile psoriatic arthritis, a condition that is an inflammatory disease of the joints often accompanied by psoriasis, in patients 2 years of age and older.

XELJANZ 1 mg/mL oral solution can be used together with methotrexate when previous treatment for polyarticular juvenile idiopathic arthritis or juvenile psoriatic arthritis was not sufficient or was not well tolerated. XELJANZ 1 mg/mL oral solution can also be taken on its own in those cases where methotrexate treatment is not tolerated or treatment with methotrexate is not advised.

2. What you need to know before you take XELJANZ

Do not take XELJANZ
- if you are allergic to tofacitinib or any of the other ingredients of this medicine (listed in section 6)
- if you have a severe infection such as bloodstream infection or active tuberculosis
- if you have been informed that you have severe liver problems, including cirrhosis (scarring of the liver)
- if you are pregnant or breast-feeding

If you are not sure regarding any of the information provided above, please contact your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking XELJANZ:

- if you think you have an infection or have **symptoms of an infection** such as fever, sweating, chills, muscle aches, cough, shortness of breath, new phlegm or change in phlegm, weight loss, warm or red or painful skin or sores on your body, difficulty or pain when swallowing, diarrhoea or stomach pain, burning when you urinate or urinating more often than normal, feeling very tired
- if you have any **condition that increases your chance of infection** (e.g., diabetes, HIV/AIDS, or a weak immune system)
- if you have **any kind of infection**, are being treated for any infection, or if you have infections that keep coming back. Tell your doctor immediately if you feel unwell. XELJANZ can reduce your body's ability to respond to infections and may make an existing infection worse or increase the chance of getting a new infection
- if you have or have a history of **tuberculosis** or have been in close contact with someone with tuberculosis. Your doctor will test you for tuberculosis before starting XELJANZ and may retest during treatment
- if you have any **chronic lung disease**
- if you have **liver problems**
- if you have or had **hepatitis B or hepatitis C** (viruses that affect the liver). The virus may become active while you are taking XELJANZ. Your doctor may do blood tests for hepatitis before you start treatment with XELJANZ and while you are taking XELJANZ
- if you have ever had **any type of cancer**, and also if you are a **current or past smoker**. XELJANZ may increase your risk of certain cancers. White blood cell cancer, lung cancer and other cancers (such as breast, skin, prostate and pancreatic) have been reported in patients treated with XELJANZ. If you develop cancer while taking XELJANZ your doctor will review whether to stop XELJANZ treatment.
- if you are at **known risk of fractures**, e.g., if you are 65 years of age and older, you are a female, or take corticosteroids (e.g., prednisone).
- Cases of **non-melanoma skin cancer** have been observed in patients taking XELJANZ. Your doctor may recommend that you have regular skin examinations while taking XELJANZ. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.
- if you have had **diverticulitis** (a type of inflammation of the large intestine) or **ulcers in stomach or intestines** (see section 4)
- if you have **kidney problems**
- if you are **planning to get vaccinated**, tell your doctor. Certain types of vaccines should not be given when taking XELJANZ. Before you start XELJANZ, you should be up to date with all recommended vaccinations. Your doctor will decide whether you need to have herpes zoster vaccination.
- if you have **heart problems, high blood pressure, high cholesterol, and also if you are a current or past smoker**

There have been reports of patients treated with XELJANZ who have developed **blood clots** in the lungs or veins. Your doctor will evaluate your risk to develop blood clots in the lungs or veins and determine if XELJANZ is appropriate for you. If you have already had problems on developing blood clots in lungs and veins or have an increased risk for developing this (for example: if you are seriously overweight, if you have cancer, heart problems, diabetes, experienced a heart attack (within previous 3 months), recent major surgery, if you use hormonal contraceptives/hormonal replacement therapy, if a coagulation defect is identified in you or your close relatives), or if you smoke currently or in the past, your doctor may decide that XELJANZ is not suitable for you.

Talk to your doctor straight away:

- if you develop **sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm**, **leg pain or tenderness, or redness or discoloration in the leg or arm** while taking XELJANZ, as these may be signs of a clot in the lungs or veins.

- if you experience **acute changes to your eyesight** (blurry vision, partial or complete loss of vision), as this may be a sign of blood clots in the eyes.
- if you develop **signs and symptoms of a heart attack** including severe chest pain or tightness (that may spread to arms, jaw, neck, back), shortness of breath, cold sweat, light headedness or sudden dizziness. There have been reports of patients treated with XELJANZ who have had a heart problem, including heart attack. Your doctor will evaluate your risk to develop a heart problem and determine if XELJANZ is appropriate for you.
- if you, your partner or your caregiver notice new onset or worsening of neurological symptoms including general muscle weakness, disturbance of vision, changes in thinking, memory and orientation leading to confusion and personality changes contact your doctor immediately because these may be symptoms of a very rare, serious brain infection called progressive multifocal leukoencephalopathy (PML).

Additional monitoring tests
Your doctor should perform blood tests before you start taking XELJANZ, and after 4 to 8 weeks of treatment and then every 3 months, to determine if you have a low white blood cell (neutrophil or lymphocyte) count, or a low red blood cell count (anaemia).

You should not receive XELJANZ if your white blood cell (neutrophil or lymphocyte) count or red blood cell count is too low. If needed, your doctor may interrupt your XELJANZ treatment to reduce the risk of infection (white blood cell counts) or anaemia (red blood cell counts).

Your doctor may also perform other tests, for example to check your blood cholesterol levels or monitor the health of your liver. Your doctor should test your cholesterol levels 8 weeks after you start receiving XELJANZ. Your doctor should perform liver tests periodically.

Elderly
The safety and efficacy of tofacitinib 1 mg/mL oral solution has not been established in the elderly.

Asian patients
There is a higher rate of shingles in Japanese and Korean patients. Tell your doctor if you notice any painful blisters on your skin.

You may also be at higher risk of certain lung problems. Tell your doctor if you notice any breathing difficulties.

Children and adolescents
This medicine should not be given to patients less than 2 years of age.

This medicine contains propylene glycol and should be used with caution in patients 2 years of age and older and only if advised by the doctor (see "XELJANZ contains propylene glycol").

Other medicines and XELJANZ
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you have **diabetes** or are **taking medicines to treat diabetes.** Your doctor may decide if you need less anti-diabetic medicine while taking tofacitinib.

Some medicines **should not be taken with XELJANZ**. If taken with XELJANZ, they could alter the level of XELJANZ in your body, and the dose of XELJANZ may require adjustment. You should tell your doctor if you are using medicines that contain any of the following active substances:
- antibiotics such as rifampicin, used to treat bacterial infections
- fluconazole, ketoconazole, used to treat fungal infections

XELJANZ is not recommended for use with medicines that depress the immune system, including so-called targeted biologic (antibody) therapies, such as those that inhibit tumour necrosis factor,

interleukin-17, interleukin-12/interleukin-23, anti-integrins, and strong chemical immunosuppressants including azathioprine, mercaptopurine, ciclosporin, and tacrolimus. Taking XELJANZ with these medicines may increase your risk of side effects including infection.

Serious infections and fractures may happen more often in people who also take corticosteroids (e.g., prednisone).

Pregnancy and breast-feeding
If you are a woman of childbearing age, you should use effective birth control during treatment with XELJANZ and for at least 4 weeks after the last dose.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. XELJANZ must not be used during pregnancy. Tell your doctor right away if you become pregnant while taking XELJANZ.

If you are taking XELJANZ and breast-feeding, you must stop breast-feeding until you talk to your doctor about stopping treatment with XELJANZ.

Driving and using machines
XELJANZ has no or limited effect on your ability to drive or use machines.

XELJANZ contains propylene glycol
This medicine contains 2.39 mg propylene glycol in each mL of oral solution.

XELJANZ contains sodium benzoate
This medicine contains 0.9 mg sodium benzoate in each mL of oral solution.

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

3. How to take XELJANZ

This medicine is provided to you and supervised by a specialised doctor who knows how to treat your condition.

Always take this medicine exactly as your doctor has told you, the recommended dose should not be exceeded. Check with your doctor or pharmacist if you are not sure.

The recommended dose in patients 2 years of age and older is based upon the following weight categories (see Table 1).

Table 1. XELJANZ dose for patients with polyarticular juvenile idiopathic arthritis and juvenile PsA two years of age and older:

Body weight (kg)	Dose regimen
10 - <20	3.2 mg (3.2 mL of oral solution) twice daily
20 - <40	4 mg (4 mL of oral solution) twice daily
≥ 40	5 mg (5 mL of oral solution or 5 mg film-coated tablet) twice daily

Your doctor may reduce the dose if you have liver or kidney problems or if you are prescribed certain other medicines. Your doctor may also stop treatment temporarily or permanently if blood tests show low white blood cell or red blood cell counts.

If you suffer from polyarticular juvenile idiopathic arthritis or juvenile psoriatic arthritis, your doctor may switch you from XELJANZ 5 mL oral solution twice daily to XELJANZ 5 mg film-coated tablets twice daily.

XELJANZ is for oral use. You can take XELJANZ with or without food.

Try to take XELJANZ at the same time every day (once in the morning and once in the evening).

If you take more XELJANZ than you should
If you take more XELJANZ 1 mg/mL oral solution than you should, **immediately** tell your doctor or pharmacist.

If you forget to take XELJANZ
Do not take a double dose to make up for a forgotten dose. Take your next dose at the usual time and continue as before.

If you stop taking XELJANZ
You should not stop taking XELJANZ without discussing this with your doctor.

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

4. Possible side effects

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

Some may be serious and need medical attention.

Side effects in patients with polyarticular juvenile idiopathic arthritis and juvenile psoriatic arthritis were consistent with those seen in adult rheumatoid arthritis patients with the exception of some infections (influenza, pharyngitis, sinusitis, viral infection) and gastrointestinal or general disorders (abdominal pain, nausea, vomiting, fever, headache, cough), which were more common in juvenile idiopathic arthritis paediatric population.

Possible serious side effects
In rare cases, infection may be life-threatening.

Lung cancer, white blood cell cancer and heart attack have also been reported.

If you notice any of the following serious side effects you need to tell a doctor straight away.

Signs of serious infections (common) include
- fever and chills
- cough
- skin blisters
- stomach ache
- persistent headaches

Signs of ulcers or holes (perforations) in your stomach (uncommon) include
- fever
- stomach or abdominal pain
- blood in the stool
- unexplained changes in bowel habits

Holes in stomach or intestines happen most often in people who also take nonsteroidal anti-inflammatory drugs or corticosteroids (e.g., prednisone).

Signs of allergic reactions (unknown) include
- chest tightness

- wheezing
- severe dizziness or light-headedness
- swelling of the lips, tongue or throat
- hives (itching or skin rash)

Signs of blood clots in lungs or veins or eyes (uncommon: venous thromboembolism) include
- sudden shortness of breath or difficulty breathing
- chest pain or pain in upper back
- swelling of the leg or arm
- leg pain or tenderness
- redness or discoloration in the leg or arm
- acute changes in eyesight

Signs of a heart attack (uncommon) include
- severe chest pain or tightness (that may spread to arms, jaw, neck, back)
- shortness of breath
- cold sweat
- light headedness or sudden dizziness

Other side effects which have been observed with XELJANZ are listed below.

Common (may affect up to 1 in 10 people): lung infection (pneumonia and bronchitis), shingles (herpes zoster), infections of nose, throat or the windpipe (nasopharyngitis), influenza, sinusitis, urinary bladder infection (cystitis), sore throat (pharyngitis), increased muscle enzymes in the blood (sign of muscle problems), stomach (belly) pain (which may be from inflammation of the stomach lining), vomiting, diarrhoea, feeling sick (nausea), indigestion, low white blood cell counts, low red blood cell count (anaemia), swelling of the feet and hands, headache, high blood pressure (hypertension), cough, rash, acne.

Uncommon (may affect up to 1 in 100 people): lung cancer, tuberculosis, kidney infection, skin infection, herpes simplex or cold sores (oral herpes), blood creatinine increased (a possible sign of kidney problems), increased cholesterol (including increased LDL), fever, fatigue (tiredness), weight gain, dehydration, muscle strain, tendonitis, joint swelling, joint sprain, abnormal sensations, poor sleep, sinus congestion, shortness of breath or difficulty breathing, skin redness, itching, fatty liver, painful inflammation of small pockets in the lining of your intestine (diverticulitis), viral infections, viral infections affecting the gut, some types of skin cancers (non-melanoma-types).

Rare (may affect up to 1 in 1,000 people): blood infection (sepsis), lymphoma (white blood cell cancer), disseminated tuberculosis involving bones and other organs, other unusual infections, joint infections, increased liver enzymes in the blood (sign of liver problems), pain in the muscles and joints.

Very rare (may affect up to 1 in 10,000 people): tuberculosis involving the brain and spinal cord, meningitis, infection of the soft tissue and fascia.

In general, fewer side effects were seen when XELJANZ was used alone than in combination with methotrexate in rheumatoid arthritis.

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 the 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 XELJANZ

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 or bottle. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original bottle and package in order to protect from light.

Discard after 60 days of first opening.

Do not use this medicine if you notice the solution shows visible signs of deterioration.

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 XELJANZ contains

- The active substance is tofacitinib.
- Each 1 mL contains 1 mg of tofacitinib (as tofacitinib citrate).
- The other ingredients are grape flavour [containing propylene glycol (E1520) (see section 2 "XELJANZ contains propylene glycol"), glycerin (E422), and natural flavours], hydrochloric acid, lactic acid (E270), purified water, sodium benzoate (E211) (see section 2 "XELJANZ contains sodium benzoate" and "XELJANZ contains sodium"), sucralose (E955), and xylitol (E967).

What XELJANZ looks like and contents of the pack

XELJANZ 1 mg/mL oral solution is a clear, colourless solution.
The 1 mg/mL oral solution is provided in white coloured HDPE 250 mL bottles containing 240 mL of solution. Each pack contains one HDPE bottle, one press-in bottle adapter, and one oral dosing syringe with 3.2 mL, 4 mL, and 5 mL graduations.

Marketing Authorisation Holder

Pfizer Limited
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CT13 9NJ
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Manufacturer

Pfizer Service Company BV
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For any information about this medicine, please contact:
Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.

Telephone 01304 616161.

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Ref: XJ 9_0 OS

For Instructions for Use of XELJANZ oral solution, please see section 7.

7. Instructions for Use of XELJANZ oral solution

Read this Instructions for Use before you start taking XELJANZ oral solution. There may be new information.

Important information about measuring XELJANZ oral solution

Always use the oral dosing syringe that comes with your XELJANZ oral solution to measure and administer your prescribed dose. Ask your healthcare provider or pharmacist to show you how to measure your prescribed dose if you are not sure.

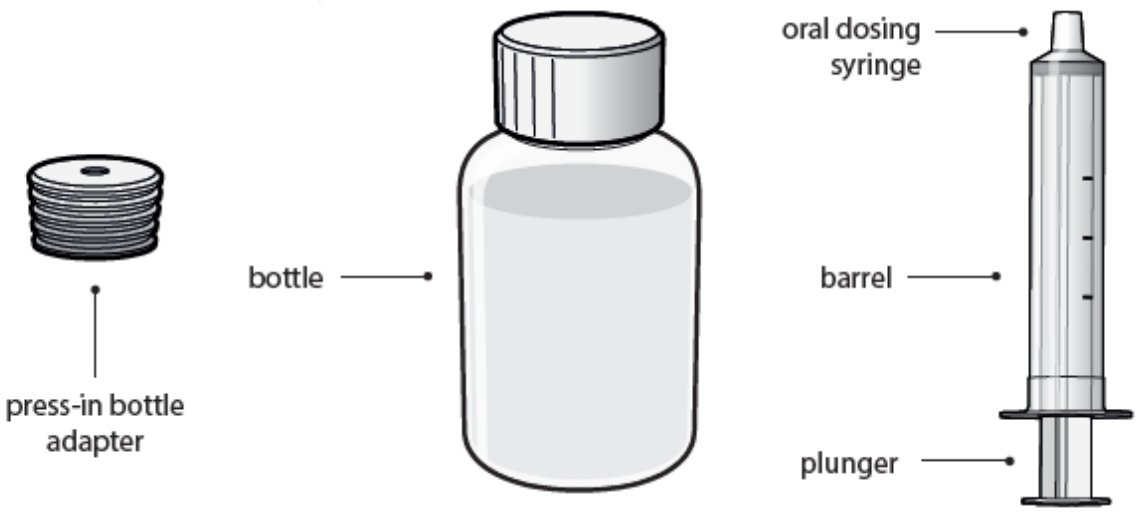
How should I store XELJANZ?

Keep this medicine out of the sight and reach of children.

Discard remaining XELJANZ oral solution after 60 days.
To help you remember when to dispose of your XELJANZ bottle you can write the date of first use on the carton and below:
Date of first use ____ / ____ / ____.

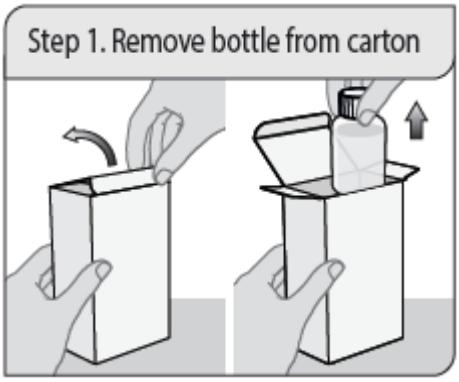
Each carton of XELJANZ oral solution contains

- 1 press-in bottle adapter
- 1 bottle of XELJANZ oral solution
- 1 oral dosing syringe



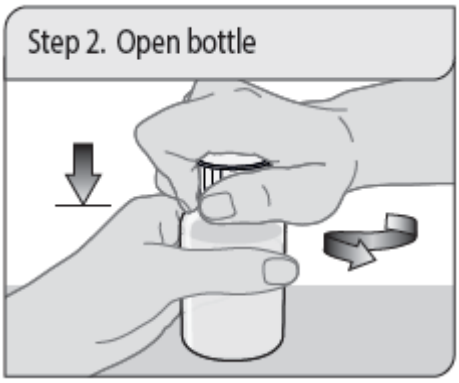
Before each use:
Wash your hands with soap and water and place the items from the carton on a clean flat surface.

Step 1. Remove bottle from carton



Remove the bottle of XELJANZ oral solution from the carton.

Step 2. Open bottle

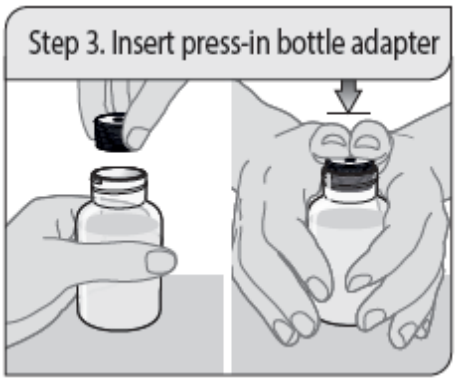


Open the bottle. Remove the seal off the top of the bottle (first time only).

Do not throw away the child-resistant cap.

Note: Bottle does **not** need to be shaken before use.

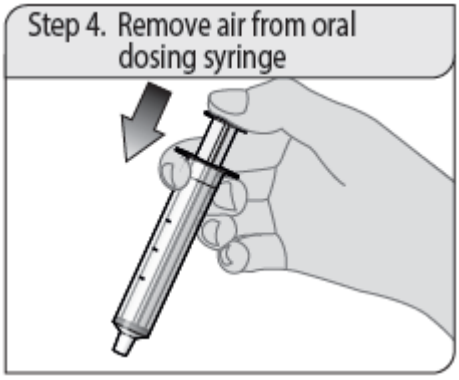
Step 3. Insert press-in bottle adapter



Remove the press-in bottle adapter and oral dosing syringe from the plastic overwrap. With the bottle on a flat surface, push the ribbed end of the press-in bottle adapter with your thumbs all the way into the neck of the bottle while holding the bottle firmly.

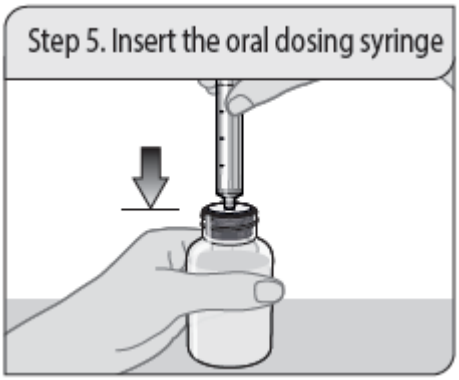
Note: Do not remove the press-in bottle adapter from the bottle after it is inserted.

Step 4. Remove air from oral dosing syringe



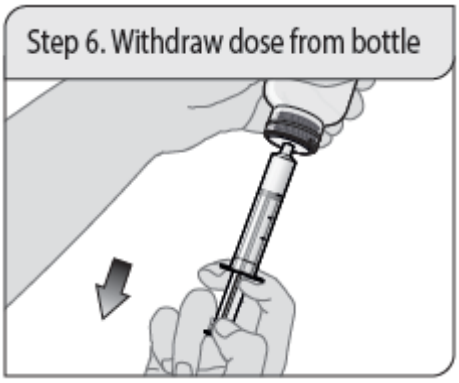
Push the oral dosing syringe plunger fully to the tip of the syringe barrel to remove excess air.

Step 5. Insert the oral dosing syringe



Insert the oral dosing syringe into the upright bottle through the opening of the press-in bottle adapter until it is firmly in place.

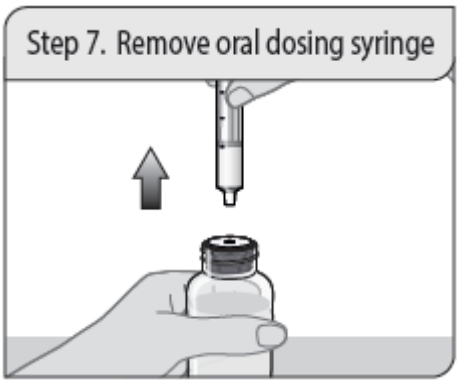
Step 6. Withdraw dose from bottle



With the oral dosing syringe in place, turn the bottle upside down. Pull back the plunger.

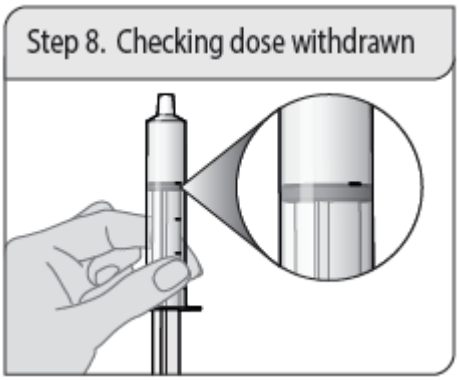
If you see air bubbles in the oral dosing syringe, fully push the plunger in to empty the oral solution back into the bottle. Then withdraw your prescribed dose of oral solution.

Step 7. Remove oral dosing syringe



Turn the bottle upright and place the bottle on a flat surface. Remove the oral dosing syringe from the bottle adapter and bottle by pulling straight up on the oral dosing syringe barrel.

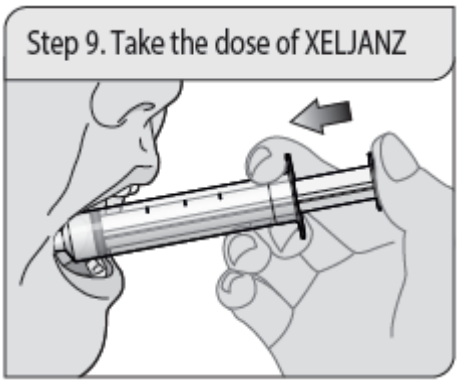
Step 8. Checking dose withdrawn



Check that the correct dose was drawn up into the oral dosing syringe.

If the dose is not correct, insert the oral dosing syringe tip firmly into the bottle adapter. Fully push in the plunger so that the oral solution flows back into the bottle. Repeat Steps 6 and 7.

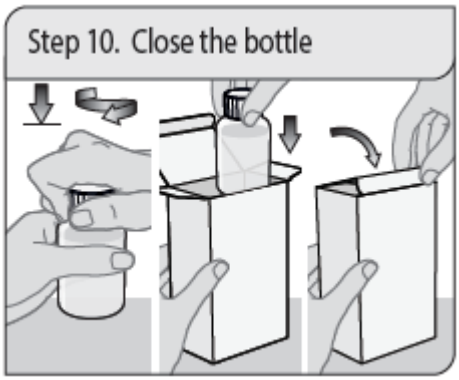
Step 9. Take the dose of XELJANZ



Place the tip of the oral dosing syringe into the inside of the patient's cheek.

Slowly push the plunger all the way down to give all the medicine in the oral dosing syringe. Make sure the patient has time to swallow the medicine.

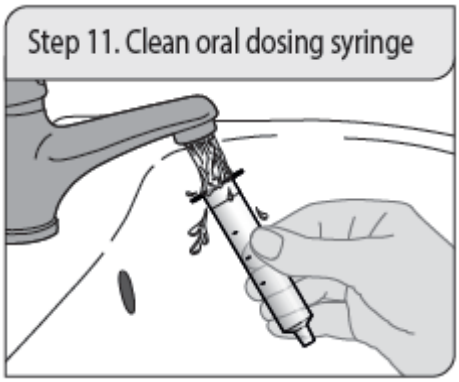
Step 10. Close the bottle



Close the bottle tightly by turning the child-resistant cap clockwise, leaving the press-in bottle adapter in place.

Place the bottle back into the carton and close the carton to protect XELJANZ oral solution from light.

Step 11. Clean oral dosing syringe



Remove the plunger from the barrel by pulling the plunger and the barrel away from each other.

Rinse both with water after each use.

Allow to air dry; then put the oral dosing syringe back together with oral solution in the carton.

Store the oral dosing syringe with the XELJANZ oral solution.

Do not throw away the oral dosing syringe.