Package leaflet: Information for the patient

Adtralza® 300 mg solution for injection in pre-filled pen
tralokinumab

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

1. What Adtralza® is and what it is used for

Adtralza contains the active substance tralokinumab.

Tralokinumab is a monoclonal antibody (a type of protein) that blocks the action of a protein called IL-13. IL-13 plays a major role in causing the symptoms of atopic dermatitis.

Adtralza is used to treat adult and adolescent patients 12 years and older with moderate-to-severe atopic dermatitis, also known as atopic eczema. Adtralza may be used with eczema medicines that you apply to the skin or it may be used on its own.

Using Adtralza for atopic dermatitis can improve your eczema and reduce the related itching and skin pain.

2. What you need to know before you use Adtralza®

Do not use Adtralza:
- if you are allergic to tralokinumab or any of the other ingredients of this medicine (listed in section 6).

If you think you may be allergic, or you are not sure, ask your doctor, pharmacist or nurse for advice before using Adtralza.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Adtralza.

Allergic reactions
Very rarely, medicines can cause allergic (hypersensitivity) reactions and severe allergic reactions called anaphylaxis. You must look out for signs of these reactions (such as breathing problems, swelling of the face, mouth, and tongue, fainting, dizziness, feeling lightheaded (because of low blood pressure), hives, itching and skin rash) while you are using Adtralza.
Stop using Adtralza and tell your doctor or get medical help immediately if you notice any signs of an allergic reaction. Such signs are listed in the beginning of section 4.

Parasitic infection in the intestines
Adtralza may reduce your resistance to infections caused by parasites. Any parasitic infection should be treated before you start treatment with Adtralza. Tell your doctor if you have diarrhoea, gas, upset stomach, greasy stools, and dehydration which could be signs of a parasitic infection. If you live in a region where these infections are common or if you are travelling to such a region, tell your doctor.

Eye problems
Talk to your doctor if you have any new or worsening eye problems, including eye pain or changes in vision.

Children
Do not give this medicine to children below the age of 12 years because the safety and benefits of Adtralza are not yet known in this population.

Other medicines and Adtralza
Tell your doctor or pharmacist
- If you are using, have recently used or might use any other medicines.
- If you have recently had a vaccination or are due to have one.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or you are planning to have a baby, ask your doctor for advice before using this medicine. The effects of Adtralza in pregnant women are not known; therefore, it is preferable to avoid using it during pregnancy unless your doctor advises you to use it.

If applicable, you and your doctor should decide if you will breast-feed or use Adtralza. You should not do both.

Driving and using machines
Adtralza is unlikely to reduce your ability to drive and use machines.

Adtralza contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 300 mg that is to say essentially "sodium-free".

Adtralza contains polysorbate (E 433)
This medicine contains 0.2 mg of polysorbate 80 in each pre-filled pen which is equivalent to 0.1 mg/ml.
Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Adtralza®

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

Each pre-filled pen contains 300 mg of tralokinumab.

How much Adtralza is given and for how long
- Your doctor will decide how much Adtralza you need and for how long.
- The recommended first dose is 600 mg (two 300 mg injections), followed by 300 mg (one 300 mg injection) given every 2 weeks. Based on how well the medicine works, your doctor may decide that you can have a dose every 4 weeks.

Adtralza is given by injection under your skin (subcutaneous injection). You and your doctor or nurse can decide if you can inject Adtralza yourself.

Inject Adtralza yourself only after you have been trained by your doctor or nurse. A caregiver may also give you your Adtralza injection after proper training.

Do not shake the pen.

Read the "Instructions for Use" before injecting Adtralza.

If you use more Adtralza than you should
If you use more of this medicine than you should or the dose has been given too early, talk to your doctor, pharmacist or nurse.

If you forget to use Adtralza
If you miss injecting a dose at the right time, inject Adtralza as soon as possible. Then the next dose should be injected at the regular scheduled time.

If you stop using Adtralza
Do not stop using Adtralza without speaking to your doctor first.

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.
Adtralza can cause serious side effects, including allergic (hypersensitivity) reactions such as anaphylaxis; the signs may include:

- breathing problems
- swelling of the face, mouth, and tongue
- fainting, dizziness, feeling lightheaded (low blood pressure)
- hives
- itching
- skin rash

Stop using Adtralza and tell your doctor or get medical help immediately if you notice any signs of allergic reaction.

Other side effects

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

- upper respiratory tract infections (i.e. common cold and sore throat)

Common (may affect up to 1 in 10 people)

- eye redness and itching
- eye infection
- injection site reactions (i.e. redness, swelling)

Uncommon (may affect up to 1 in 100 people)

- eye inflammation which may cause eye pain or decreased vision

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 at: 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 Adtralza®

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

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

Store in a refrigerator (2 °C to 8 °C). Do not freeze.
If necessary, Adtralza may be kept at room temperature up to 30 °C in the original package for a maximum of 14 days. Do not store above 30 °C. Throw away Adtralza if it is not used within 14 days of storage at room temperature.

If you need to permanently remove the carton from the refrigerator, write down the date of removal on the carton, and use Adtralza within 14 days. Adtralza must not be refrigerated again during this period.

Do not use this medicine if you notice that it is cloudy, discoloured or has particles in it.
Do not throw away any medicines via wastewater or household waste. Ask your doctor, pharmacist or nurse 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 Adtralza contains
- The active substance is tralokinumab.
- Each pre-filled pen contains 300 mg of tralokinumab in 2 ml solution for injection.
- The other ingredients are sodium acetate trihydrate (E 262), acetic acid (E 260), sodium chloride, polysorbate 80 (E 433) and water for injections.

What Adtralza looks like and contents of the pack
Adtralza is a clear to opalescent, colourless to pale yellow solution, supplied in a pre-filled pen.

Adtralza is available in unit packs containing 2 pre-filled pens or in multipacks containing 6 (3 packs of 2) pre-filled pens.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
LEO Laboratories Ltd
Tel: +44 (0) 1844 347333

This leaflet was last revised in February 2026

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

The Instructions for Use with information about on how to inject Adtralza is shown on the other side of this leaflet.

For information in large print, Braille or audio/CD, telephone +44 (0)1844 347333.

Instructions for Use
Adtralza®300 mg solution for injection in pre-filled pen
tralokinumab

Read these instructions before you start using Adtralza pre-filled pens and each time you get a new package. There may be new information. You should also talk to your healthcare professional about your medical condition or your treatment.

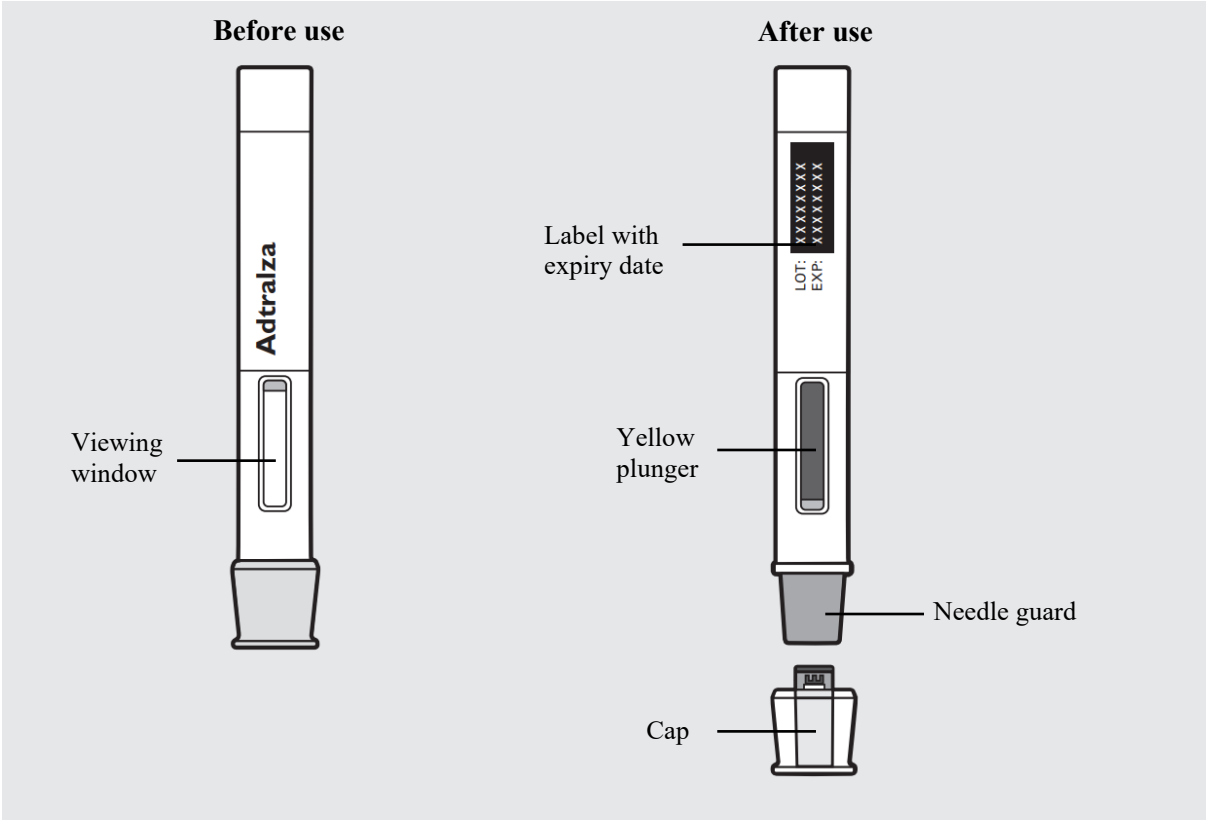
Keep this Instructions for Use so you can read it again if necessary.

Each pre-filled pen contains 300 mg of tralokinumab.
The Adtralza pre-filled pens are for single-use only.

IMPORTANT INFORMATION
Important information you need to know before injecting Adtralza:

- Before you inject Adtralza for the first time, your healthcare professional will show you how to prepare and inject Adtralza using the pre-filled pen.
- **Do not** inject Adtralza until you have been shown how to inject it the right way.
- Talk to your healthcare professional if you have any questions about how to inject Adtralza the right way.
- **To receive your full dose, you will need to have 1 Adtralza injection.**
- **It is recommended that you use a different injection area for each new injection.**
- The Adtralza pre-filled pen has a needle guard that will automatically cover the needle after the injection is finished.
- **Do not** remove the cap until just before you give the injection.
- **Do not** share or reuse your Adtralza pre-filled pens.

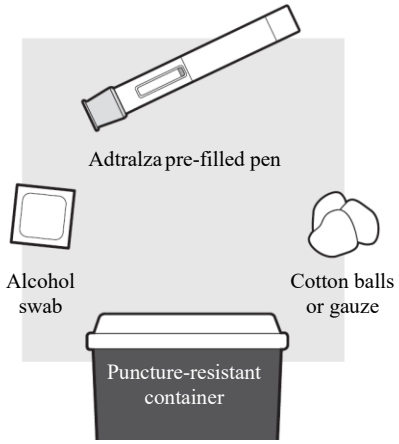
Adtralza pre-filled pen parts:



How to store Adtralza

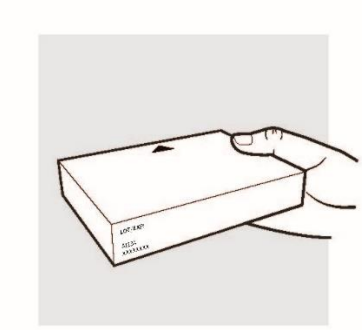
- **Keep this medicine out of the sight and reach of children. Contains small parts.**
- Store Adtralza pre-filled pens in a refrigerator between 2 ºC and 8 ºC.
- Store Adtralza pre-filled pens in the original package and protect from light until you are ready to use them.
- **Do not** freeze Adtralza pre-filled pens. **Do not** use if they have been frozen.
- Adtralza can be stored in the original package at room temperature up to 30°C for up to 14 days. If removed permanently from the refrigerator, write down the date of removal on the carton, and use Adtralza within 14 days. Discard pens if left out of the refrigerator for more than 14 days.

Step 1: Setting up Adtralza injection



1a: Gather the supplies needed for your injection
For each Adtralza dose you will need:

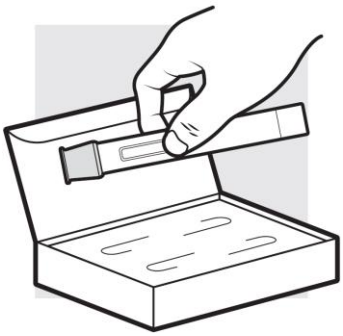
- A clean, flat, well-lit work surface, like a table
- 1 Adtralza pre-filled pen
- An alcohol swab (not included in the carton)
- Clean gauze pads or cotton balls (not included in the carton)
- A puncture-resistant sharps disposal container (not included in the carton)



1b: Take the Adtralza carton out of the refrigerator

- **Check the expiry date (EXP) on the carton. Do not** use if the expiry date on the carton has passed.
- When using the first pre-filled pen in the carton, check to make sure the seal on the carton is intact. **Do not** use the Adtralza pre-filled pens if the seal on the carton is broken.

Do not use the Adtralza pre-filled pens if the pre-filled pens have been stored at room temperature for more than 14 days.

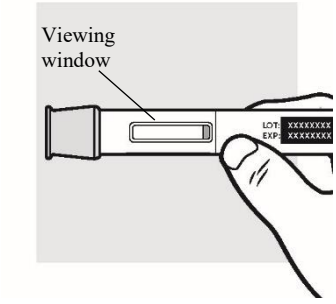


1c: Remove the Adtralza pre-filled pen from the carton
Remove **1** pre-filled pen from the carton. When using the first pre-filled pen, put the carton with the remaining pre-filled pen back in the refrigerator.

- **Do not** remove the cap on the pre-filled pen until you have reached Step 3 and are ready to inject.

1d: Let the Adtralza pre-filled pen reach room temperature
Place the pre-filled pen on the flat surface and wait at least 45 minutes before you inject Adtralza to let the pre-filled pen reach room temperature (20 ºC to 30 ºC). This will help to make injection of Adtralza more comfortable.

- **Do not** heat the pre-filled pen in any way.
- **Do not** shake the pre-filled pen.
- **Do not** put the pre-filled pen back in the refrigerator once it has reached room temperature.



1e: Inspect the Adtralza pre-filled pen

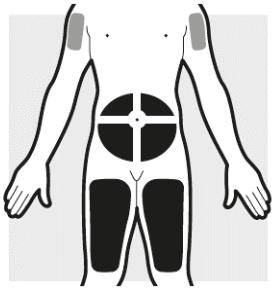
- Make sure the label shows the correct name of the medicine, Adtralza.
- Check the expiry date on the pre-filled pen label.
- Check the medicine through the viewing window. The medicine should be clear to opalescent, colourless to pale yellow.
- You may see small air bubbles in the liquid. This is normal. You do not need to do anything about it.

- Do not use the Adtralza pre-filled pen if:
  - the expiry date on the pre-filled pen has passed

- the medicine is cloudy, discoloured, or has particles in it
- the pre-filled pen looks damaged or has been dropped

If you cannot use the pre-filled pen, dispose of it in a puncture-resistant container and use a new pre-filled pen.

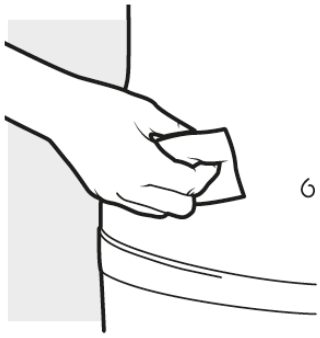
Step 2: Choosing and preparing injection area



Injection by caregiver only
Self-injection or by caregiver

2a: Choose the area for your injection

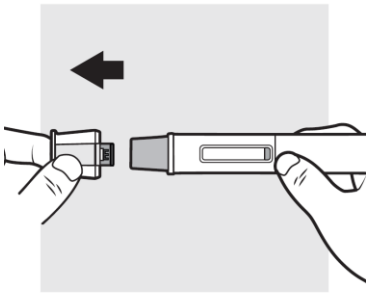
- You may inject into:
  - your stomach area (abdomen)
  - your thighs
  - your upper arm. To inject into your upper arm, you will need a caregiver to give you the injection.
- **Do not** inject where the skin is tender, bruised, scaly, scarred, damaged, hard or covered with eczema.
- **Do not** inject within 5 cm of your belly button (navel).
- **It is recommended that you use a different injection area for each new injection. Do not use the same body area 2 times in a row.**



2b: Wash your hands and prepare your skin

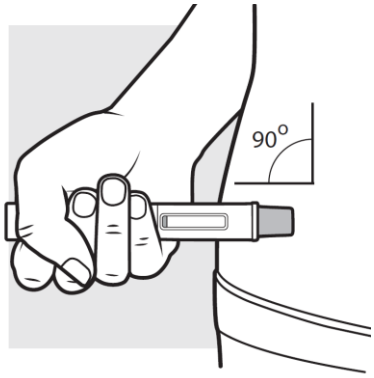
- Wash your hands with soap and water.
- Clean the injection area with an alcohol swab using a circular motion.
  - Let the area dry completely.
  - **Do not** blow on or touch the cleaned area before injecting.

Step 3: Injecting Adtralza



3a: Pull off the Adtralza cap
Hold the pre-filled pen with one hand, pull the cap straight off with your other hand and throw it into the puncture-resistant container. The needle guard is now exposed. It is there to prevent you from touching the needle.

- **Do not try to recap the pre-filled pen.** This could cause the injection to happen too soon or damage the needle.
- **Do not** try to touch or push on the needle guard with your finger. This could cause needle stick injury.



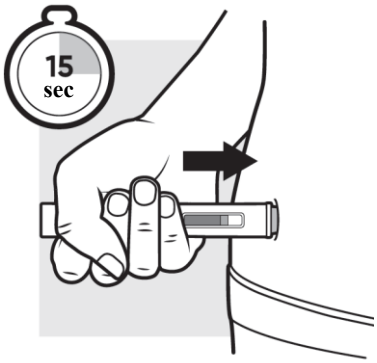
3b: Place the Adtralza pre-filled pen at the injection site so that you can see the viewing window

You can gently pinch the skin where you cleaned the injection area or give the injection without pinching the skin. Follow your healthcare professional´s instructions on how to inject.

- Place the needle guard of the pre-filled pen flat against your skin (90-degree angle) at the injection site you have cleaned. Make sure you can see the viewing window.

- **Do not** change the position of the pre-filled pen after the injection has started.

If the pre-filled pen is removed too soon, you may see a stream of medicine coming from the pre-filled pen. If this happens you may not have received your full dose. Call your doctor, pharmacist or nurse.



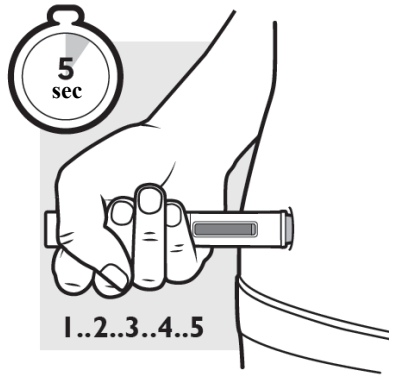
3c: Press down on the Adtralza pre-filled pen and hold pressure

Press the pre-filled pen down firmly and hold it in place. You will hear a **"click"** to let you know that the injection has started and the yellow plunger will start to move.

The yellow plunger will move to the bottom of the viewing window as the medicine is being injected. **It may take up to 15 seconds to inject the full dose**.

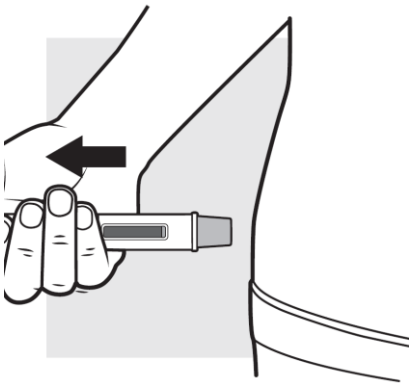
You will hear a second **"click"** when the yellow plunger fills the viewing window.

Keep pressing.



3d: Continue to press down for another 5 seconds

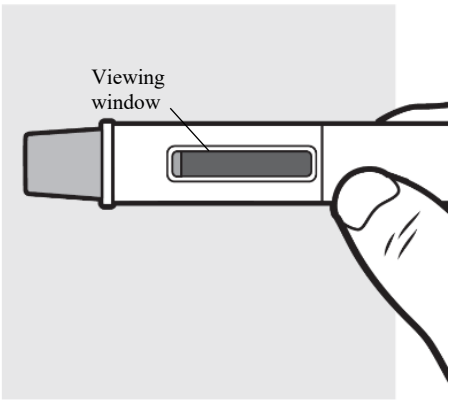
After the second "click", continue to press the pen firmly against your skin for 5 seconds to make sure you get your full dose.



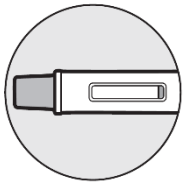
3e: Remove the Adtralza pre-filled pen

Pull the pre-filled pen straight away from the injection site. The needle guard will slide down and lock into place over the needle.

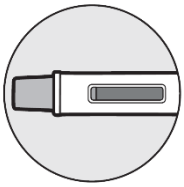
- Place a dry cotton ball or gauze pad over the injection site for a few seconds. **Do not** rub the injection site.
- There may be a small amount of blood or liquid where you injected. This is normal. If needed, cover the injection area with a small bandage.



Before use:



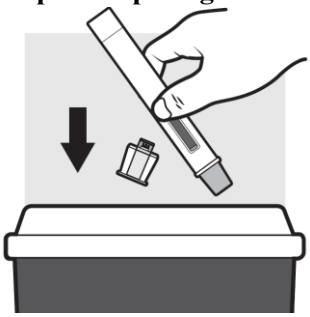
After use:



3f: Check the viewing window

Check the viewing window to make sure all the liquid has been injected.
If the yellow plunger does not fill the viewing window you may not have received the full dose. If this happens or if you have any other concerns, call your doctor, pharmacist or nurse.

Step 4: Disposing of Adtralza pre-filled pen



- Put the used Adtralza pre-filled pen in a puncture-resistant container straight away after use.
  - **Do not** throw the Adtralza pre-filled pen in your household trash.

- If you do not have a puncture-resistant container, you may use a household container that is:
  - made of heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,

    - leak-resistant, and
    - properly labelled to warn of hazardous waste inside the container.
- When your puncture-resistant container is almost full, you will need to follow your community guidelines for the right way to dispose of your puncture-resistant container.
- **Do not** recycle your used puncture-resistant container.