

**PATIENT INFORMATION LEAFLET for DUPIXENT**

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S4**

**DUPIXENT® 300 mg solution for injection**

**Dupilumab**

Contains sugar (100 mg sucrose per 2 mL solution).

**Read all of this leaflet carefully before you start using DUPIXENT.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DUPIXENT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

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

**1. What DUPIXENT is and what it is used for**

DUPIXENT is an injectable prescription medicine that inhibits IL-4 and IL-13 proteins by blocking a shared receptor.

DUPIXENT is used to treat adult patients with moderate-to-severe atopic dermatitis (also known as

eczema, a type of inflammation of your skin resulting in itchy, red, swollen and cracked skin) whose disease is not adequately controlled with prescription therapies applied as creams or ointments; or when those therapies are not advisable.

DUPIXENT can be used with or without other topical therapies (therapies applied as creams or ointments).

## **2. What you need to know before you use DUPIXENT**

### **Do not use DUPIXENT:**

- if you are hypersensitive (allergic) to dupilumab or any of the other ingredients of DUPIXENT (see section 6).

### **Warnings and precautions:**

#### **Tell your doctor or healthcare professional before being given the injection:**

- if you have had a previous hypersensitivity (allergic) reaction when you were given DUPIXENT.
- if you have a helminth infection (parasitic worms that infect your intestine).
- if you suffer from other allergic or atopic conditions such as asthma.

### ***Allergic reactions***

- DUPIXENT can cause serious side effects, including allergic (hypersensitivity) reactions and anaphylactic reactions and angioedema. These reactions can occur from minutes to days after DUPIXENT administration. You must look out for signs of these conditions (i.e. breathing problems, swelling of the face, lips, mouth, throat or tongue, fainting, dizziness, feeling lightheaded (low blood pressure), fever, general ill feeling, swollen lymph nodes, hives, itching, joint pain, skin rash) while you are using DUPIXENT. Such signs are listed in section 4.
- Stop using DUPIXENT and tell your doctor or get medical help immediately if you notice any signs of an allergic reaction.

### ***Eye problems***

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

in vision.

### **Children and adolescents:**

DUPIXENT should not be used in children (younger than 18 years).

### **Other medicines and DUPIXENT:**

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you have recently had or are due to have a vaccination.

### **Pregnancy and breastfeeding:**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using DUPIXENT.

The effects of this medicine in pregnant women are not known; therefore, it is recommended to avoid the use of DUPIXENT in pregnancy.

Tell your doctor, pharmacist or healthcare professional if you become pregnant while using DUPIXENT.

Women receiving DUPIXENT are advised to not breastfeed their babies. You and your doctor should decide if you will breastfeed or use DUPIXENT. You should not do both.

### **Driving and using machines**

DUPIXENT is unlikely to influence your ability to drive or use machines.

### **DUPIXENT contains sucrose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using DUPIXENT.

### **3. How to use DUPIXENT**

Do not share medicines prescribed for you with any other person.

Always use DUPIXENT exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week, for adult patients. Your dosage may be increased to 300 mg (one single injection) per week. Your doctor will prescribe the dosing regimen that is best for you.

DUPIXENT should not be used in children (younger than 18 years).

DUPIXENT comes as a single-dose (1 time use) pre-filled syringe with or without a needle shield.

Your doctor will prescribe the type that is best for you.

DUPIXENT is given as an injection under the skin (subcutaneous).

If your doctor decides that you or a caregiver can give the DUPIXENT injections, you or your caregiver should receive training on the right way to prepare and administer DUPIXENT. Do not try to inject DUPIXENT until you have been shown the right way by your doctor or healthcare professional (see INSTRUCTIONS FOR USE).

DUPIXENT can be injected into the thigh or abdomen, except for the 5 cm around the navel. If somebody else administers the injection, the upper arm can also be used. It is recommended to rotate the injection site with each injection. DUPIXENT should not be injected into skin that is tender, damaged or has bruises or scars.

Always check the label of your syringe before each injection to make sure you have the correct medicine.

### **If you use more DUPIXENT than you should**

Contact your doctor if you inject more DUPIXENT than you should.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

### **If you missed a dose of DUPIXENT**

Do not inject a double dose to make up for forgotten individual doses.

If you forget to inject DUPIXENT, then administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time.

### **Effects when treatment with DUPIXENT is stopped**

It is important that you do not stop using DUPIXENT without talking to your doctor or pharmacist first.

## **4. Possible side effects**

DUPIXENT can have side effects.

Not all side effects reported for DUPIXENT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DUPIXENT, please consult your doctor, pharmacist or other health care provider for advice.

DUPIXENT can cause serious side effects, including generalised allergic (hypersensitivity) reactions. If any of the following happens, stop using DUPIXENT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, tongue, mouth or throat, which may cause difficulty in swallowing or breathing (angioedema)
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction

to DUPIXENT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- eye infection
- inflammation of the eye surface, sometimes with blurred vision (keratitis, ulcerative keratitis)
- eye dryness, redness and/or itching
- eyelid itching, redness and/or swelling
- injection site reactions (swelling, redness and/or pain at the injection site)
- cold sores (e.g. on lips and skin)
- joint pain (arthralgia)
- facial rash or redness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### **Reporting of side effects:**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: [za.drugsafety@sanofi.com](mailto:za.drugsafety@sanofi.com) (email) or 011 256 3700 (tel), or
- SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of DUPIXENT.

## **5. How to store DUPIXENT**

**Store all medicines out of reach of children.**

Store refrigerated at 2 °C to 8 °C in the original carton to protect from light.

If necessary, pre-filled syringes may be kept at room temperature up to 25 °C for a maximum of 14 days. Do not store above 25 °C. After removal from the refrigerator, the product must be used within 14 days or discarded.

If you need to permanently remove the carton from the refrigerator, write down the date of removal in the space provided on the outer carton, and use DUPIXENT within 14 days.

Do not freeze.

Do not expose to heat.

Do not shake.

Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Any waste material should be disposed of in accordance with local requirements.

## **6. Contents of the pack and other information**

### **What DUPIXENT contains:**

The active substance is dupilumab.

Each DUPIXENT pre-filled syringe and DUPIXENT pre-filled syringe with needle shield contains 300 mg of dupilumab in 2 mL solution for injection.

The other ingredients are L-arginine hydrochloride (25 mM), L-histidine (20 mM), polysorbate 80 (0,2 % *m/v*), sodium acetate (12,5 mM), sucrose (5 % *m/v*), and water for injection, adjusted to Ph 5,9 with acetic acid.

### **What DUPIXENT looks like and contents of the pack:**

DUPIXENT is supplied as a sterile, preservative-free, clear to slightly opalescent, colourless to pale yellow solution for subcutaneous injection, with no visible particulate matter.

#### *DUPIXENT pre-filled syringe:*

DUPIXENT is provided as a single dose in a 2,25 mL siliconised clear Type I glass pre-filled syringe with a fixed 27 gauge 1,27 cm, thin wall stainless steel staked needle, a grey bromobutyl elastomeric plunger stopper and a grey styrene-butadiene elastomeric needle shield with or without a transparent rigid polypropylene cap.

*DUPIXENT pre-filled syringe with needle shield:*

DUPIXENT is provided as a single dose in the pre-filled syringe, with a white polycarbonate plunger rod, a white polycarbonate finger flange, and a safety system consisting of a polycarbonate needle guard with a galvanized steel spring.

Each cardboard box contains 1 or 2 pre-filled syringe/s.

Not all pack sizes are marketed.

**Holder of the certificate of registration:**

sanofi-aventis south africa (pty) ltd

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**This leaflet was last revised in:**

13 December 2021

**Registration number:**

51/13.12/0879



## INSTRUCTIONS FOR USE

### DUPIXENT 300 mg pre-filled syringe

Read the INSTRUCTIONS FOR USE before using the DUPIXENT pre-filled syringe.

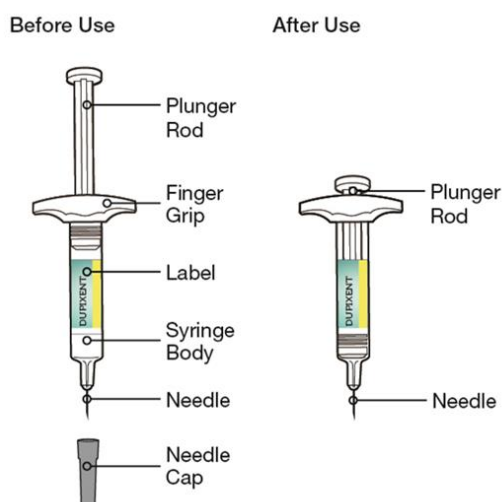
This device is a single-dose pre-filled syringe (called “syringe” in these instructions). It contains 300 mg of DUPIXENT for injection under the skin (subcutaneous injection).

Do not inject yourself or someone else until you have been shown how to inject DUPIXENT.

Your healthcare provider can show you or your caregiver how to prepare and inject a dose of DUPIXENT before you try to do it yourself for the first time.

Keep these instructions for future use.

The parts of the DUPIXENT syringe are shown in this picture.



## IMPORTANT INFORMATION

It is important that you do not try to give yourself or someone else the injection unless you have received training from your doctor or healthcare professional:

- Read all the instructions carefully before using the syringe.
- Ask your doctor or healthcare professional how often you will need to inject the medicine.
- Ask your doctor or healthcare professional to show you the right way to use the syringe before you inject for the first time.
- Rotate the injection site each time you inject.
- **Do not** use the syringe if it has been damaged.

- **Do not** use the syringe if the needle cap is missing or not securely attached.
- **Do not** touch the plunger rod until you are ready to inject.
- **Do not** inject through clothes.
- **Do not** get rid of any air bubbles in the syringe.
- **Do not** pull back on the plunger rod at any time.
- **Do not** re-use the syringe.

## HOW TO STORE DUPIXENT

Keep the syringe(s) out of the reach of children.

Keep unused syringes in the original carton and store in the refrigerator between 2 °C and 8 °C.

Remove the syringe from the refrigerator at least 45 minutes before your injection so that it reaches room temperature.

**Do not** keep DUPIXENT at room temperature for more than 14 days.

**Do not** shake the syringe at any time.

**Do not** heat the syringe.

**Do not** freeze the syringe.

**Do not** put the syringe into direct sunlight.

## STEP 1: REMOVE

Remove the syringe from the carton by holding the middle of the syringe body.

- **Do not** pull off the needle cap until you are ready to inject.
- **Do not** use the syringe if it has been damaged.



## STEP 2: PREPARE

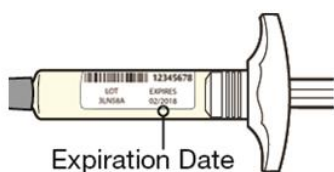
Ensure you have the following:

- The DUPIXENT pre-filled syringe
- 1 alcohol wipe\*
- 1 cotton ball or gauze\*
- A sharps disposal container\* (see Step 12)

\* Items not included in the carton

Look at the label:

- Check the expiration date. **Do not** use the syringe if the expiration date has passed.
- Check that you have the correct product and dose.



## STEP 3: INSPECT

Look at the medicine in the syringe:

- Check if the liquid is clear and colourless to pale yellow.

Note: you may see an air bubble; this is normal.

- **Do not** use the syringe if the liquid is discoloured or cloudy, or if it contains visible flakes or particles.

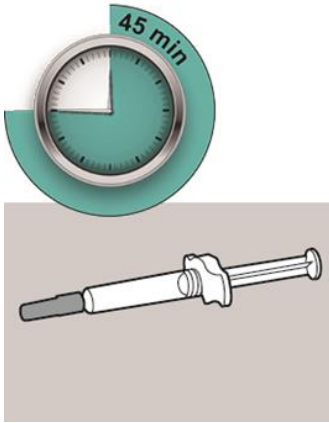


## STEP 4: WAIT 45 MINUTES

Lay the syringe on a flat surface and let it naturally warm to room temperature for at least

45 minutes.

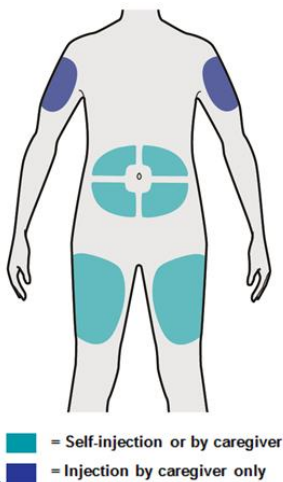
- **Do not** heat the syringe.
- **Do not** put the syringe into direct sunlight.
- **Do not** keep DUPIXENT at room temperature for more than 14 days.



### STEP 5: CHOOSE

Select the injection site.

- You can inject into your thigh or stomach, except for the 5 cm around your navel.
- If somebody else gives you the injection, you can also use the upper arm.
- **Do not** inject into skin that is tender, damaged or has bruises or scars.



### STEP 6: CLEAN

Wash your hands.

Clean the injection site with an alcohol wipe.

Let your skin dry before injecting.

**Do not** touch the injection site again or blow on it before the injection.

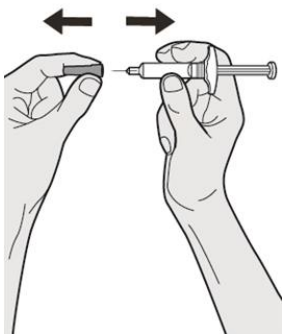


### **STEP 7: PULL**

Hold the syringe in the middle of the syringe body with the needle pointing away from you and pull off the needle cap.

- **Do not** put the needle cap back on.
- **Do not** touch the needle.

Inject your medicine immediately after removing the needle cap.



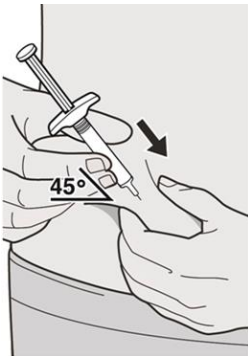
### **STEP 8: PINCH**

Pinch a fold of skin at the injection site, as shown in the picture.



### **STEP 9: INSERT**

Insert the needle into the fold of skin at roughly a 45-degree angle.



### **STEP 10: PUSH**

Relax the pinch.

Push the plunger rod down slowly and steadily as far as it will go until the syringe is empty.

*Note: You will feel some resistance. This is normal.*



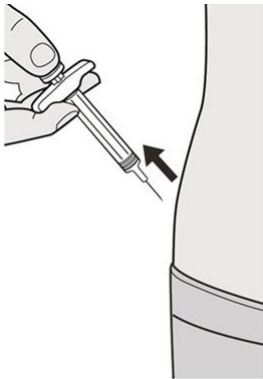
### **STEP 11: REMOVE**

Pull the needle out of the skin at the same angle it was inserted.

- **Do not** put the needle cap back on.

Lightly press a cotton ball or gauze on the injection site if you see any blood.

- **Do not** rub your skin after the injection.



## STEP 12: DISPOSE

Dispose of the syringe and the needle cap in a puncture-resistant container.

- **Do not** put the needle cap back on.
- Always keep the container out of the reach of children.



## INSTRUCTIONS FOR USE

### DUPIXENT 300 mg pre-filled syringe with needle shield

Read the INSTRUCTIONS FOR USE before using the DUPIXENT pre-filled syringe.

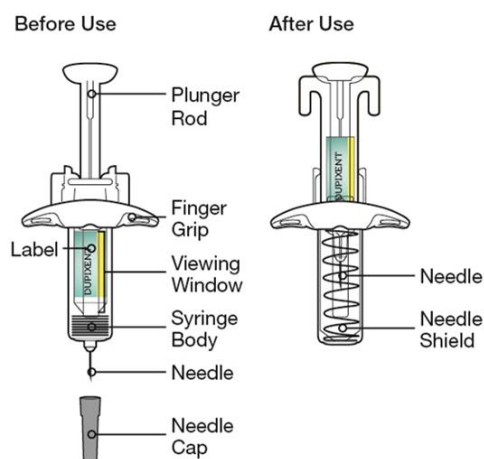
This device is a single-dose pre-filled syringe (called “syringe” in these instructions). It contains 300 mg of DUPIXENT for injection under the skin (subcutaneous injection).

Do not inject yourself or someone else until you have been shown how to inject DUPIXENT.

Your healthcare provider can show you or your caregiver how to prepare and inject a dose of DUPIXENT before you try to do it yourself for the first time.

Keep these instructions for future use.

The parts of the DUPIXENT syringe are shown in this picture.



## IMPORTANT INFORMATION

It is important that you do not try to give yourself or someone else the injection unless you have received training from your doctor or healthcare professional:

- Read all the instructions carefully before using the syringe.
- Ask your doctor or healthcare professional how often you will need to inject the medicine.
- Ask your doctor or healthcare professional to show you the right way to use the syringe before you inject for the first time.
- Rotate the injection site each time you inject.
- **Do not** use the syringe if it has been dropped on a hard surface or damaged.
- **Do not** use the syringe if the needle cap is missing or not securely attached.



- **Do not** touch the plunger rod until you are ready to inject.
- **Do not** inject through clothes.
- **Do not** get rid of any air bubbles in the syringe.
- To reduce the risk of accidental needle sticks, each pre-filled syringe has a needle shield that is automatically activated to cover the needle after you have given your injection.
- **Do not** pull back on the plunger rod at any time.
- **Do not** re-use the syringe.

## **HOW TO STORE DUPIXENT**

Keep the syringe(s) out of the reach of children.

Keep unused syringes in the original carton and store in the refrigerator between 2 °C and 8 °C.

Remove the syringe from the refrigerator at least 45 minutes before your injection so that it reaches room temperature.

**Do not** keep DUPIXENT at room temperature for more than 14 days.

**Do not** shake the syringe at any time.

**Do not** heat the syringe.

**Do not** freeze the syringe.

**Do not** put the syringe into direct sunlight.

## **STEP 1: REMOVE**

Remove the syringe from the carton by holding the middle of the syringe body.

- **Do not** pull off the needle cap until you are ready to inject.
- **Do not** use the syringe if it has been dropped on a hard surface or damaged.



## STEP 2: PREPARE

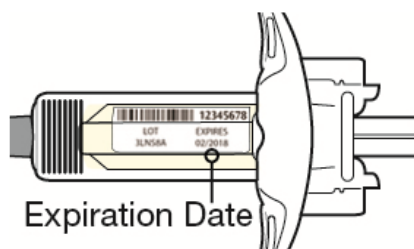
Ensure you have the following:

- The DUPIXENT pre-filled syringe
- 1 alcohol wipe\*
- 1 cotton ball or gauze\*
- A sharps disposal container\* (see Step 12)

\* Items not included in the carton

Look at the label:

- Check the expiration date. **Do not** use the syringe if the expiration date has passed.
- Check that you have the correct product and dose.



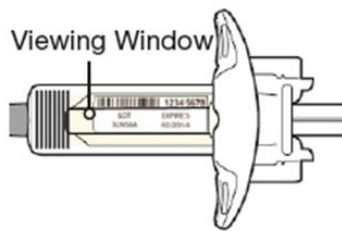
## STEP 3: INSPECT

Look at the medicine through the viewing window on the syringe:

- Check if the liquid is clear and colourless to pale yellow.

Note: you may see an air bubble; this is normal.

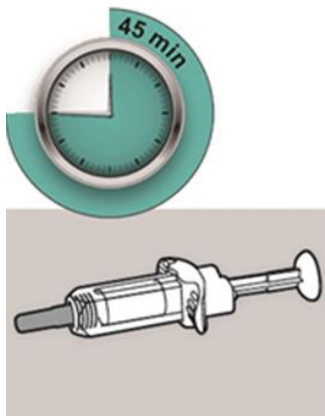
- **Do not** use the syringe if the liquid is discoloured or cloudy, or if it contains visible flakes or particles.



#### STEP 4: WAIT 45 MINUTES

Lay the syringe on a flat surface and let it naturally warm to room temperature for at least 45 minutes.

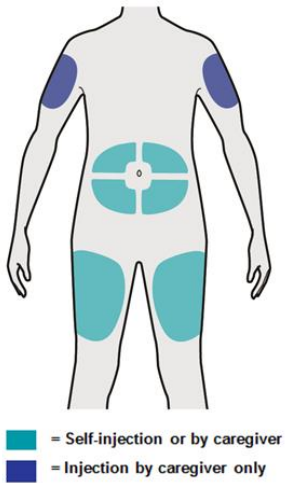
- **Do not** heat the syringe.
- **Do not** put the syringe into direct sunlight.
- **Do not** keep DUPIXENT at room temperature for more than 14 days.



#### STEP 5: CHOOSE

Select the injection site.

- You can inject into your thigh or stomach, except for the 5 cm around your navel.
- If somebody else gives you the injection, you can also use the upper arm.
- Do not inject into skin that is tender, damaged or has bruises or scars.



## STEP 6: CLEAN

Wash your hands.

Clean the injection site with an alcohol wipe.

Let your skin dry before injecting.

**Do not** touch the injection site again or blow on it before the injection.



## STEP 7: PULL

Hold the syringe in the middle of the syringe body with the needle pointing away from you and pull off the needle cap.

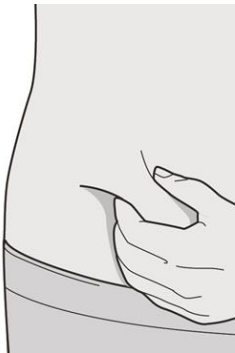
- **Do not** put the needle cap back on.
- **Do not** touch the needle.

Inject your medicine immediately after removing the needle cap.



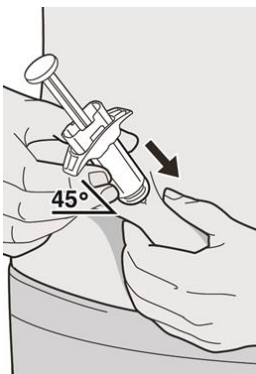
### **STEP 8: PINCH**

Pinch a fold of skin at the injection site, as shown in the picture.



### **STEP 9: INSERT**

Insert the needle completely into the fold of skin at roughly a 45-degree angle.



### **STEP 10: PUSH**

Relax the pinch.

Push the plunger rod down slowly and steadily as far as it will go until the syringe is empty.

*Note: You will feel some resistance. This is normal.*



### STEP 11: RELEASE AND REMOVE

Lift your thumb to release the plunger rod until the needle is covered by the needle shield and then remove the syringe from the injection site.

Lightly press a cotton ball or gauze on the injection site if you see any blood.

- **Do not** put the needle cap back on.
- **Do not** rub your skin after the injection.



### STEP 12: DISPOSE

Dispose of the syringe and the needle cap in a puncture-resistant container.

- **Do not** put the needle cap back on.
- Always keep the container out of the reach of children.

