

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using EPIPEN?

EPIPEN contains the active ingredient adrenaline (epinephrine). EPIPEN is only to be used for the immediate EMERGENCY TREATMENT of a SEVERE ALLERGIC REACTION (also known as ANAPHYLAXIS). For more information, see Section [1. Why am I using EPIPEN?](#) in the full CMI.

2. What should I know before I use EPIPEN?

EPIPEN is a life-saving treatment in the emergency management of severe allergic reactions. Therefore, it should not be withheld from anyone who is considered to need it. **It is important to know how to use an EPIPEN BEFORE a severe allergic reaction causes a medical emergency. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use EPIPEN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EPIPEN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use EPIPEN?

EPIPEN delivers one measured dose of adrenaline intended for a person who weighs 30 kg or more. It may be prescribed for a child who weighs between 15 kg and 30 kg.

More instructions can be found in Section [4. How do I use EPIPEN?](#) in the full CMI.

5. What should I know while using EPIPEN?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using EPIPEN. - Check the expiry date on EPIPEN and request for replacement prior to the expiry date.
Things you should not do	- Do not use EPIPEN to treat any other medical conditions including other types of shock unless advised by the doctor. - Do not use EPIPEN if the solution is cloudy, coloured, contains sediment or the viewing window is obscured. - Do not take off the blue safety release until required. - Do not touch the orange end on any person or object while you are taking off the blue safety release and/or after you have taken off the blue safety release. - Do not inject into hands, feet, ears, nose, buttocks, genital area or into blood vessels.
Driving or using machines	Your ability to drive and use machines may be affected by the anaphylactic reaction and possible adverse effects to adrenaline.
Drinking alcohol	Alcohol may increase the effects of this medicine.
Looking after your medicine	- Keep the Auto-Injector in the protective carry tube until required. Protect from light. - Store below 25°C. Temperature excursions between 15°C to 25°C permitted. Do not refrigerate.

For more information, see Section [5. What should I know while using EPIPEN?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you experience a fast or noticeable heartbeat, difficulty breathing, chest pain or shortness of breath. **This is not a complete list of all possible side effects.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

EPIPEN®

Active ingredient(s): *adrenaline (epinephrine)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using EPIPEN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EPIPEN.**

Where to find information in this leaflet:

1. [Why am I using EPIPEN?](#)
2. [What should I know before I use EPIPEN?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use EPIPEN?](#)
5. [What should I know while using EPIPEN?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using EPIPEN?

EPIPEN contains the active ingredient adrenaline (epinephrine). Adrenaline belongs to a group of medicines called adrenergic and dopaminergic agents which are classified as cardiac stimulants. In some countries, adrenaline is known as epinephrine.

Adrenaline is a natural hormone released in response to stress. Adrenaline is known to:

- shrinks abnormally wide blood vessels and
- makes the heart beat strongly

This helps improve the very low blood pressure and poor circulation that occur in a severe allergic reaction.

Adrenaline also:

- relaxes the lungs. This eases breathing and lessens wheezing.
- helps stop:
 - o swelling, for example, of the face, lips, throat, tongue, hands and feet;
 - o skin rash and/or
 - o itching

EPIPEN is only to be used for the immediate EMERGENCY TREATMENT of a SEVERE ALLERGIC REACTION (also known as ANAPHYLAXIS). Your doctor or pharmacist will explain what this is like, so that you know when you must use EPIPEN.

EPIPEN is used to treat people who have a severe allergic reaction caused by, for example, hypersensitivity to

- food
- medicines
- stinging insects
- insect bites
- latex or
- other allergens, possibly unidentified.

See Section [6. Are there any side effects?](#) for information regarding allergy to sodium metabisulfite.

Avoidance of known allergens is most important in preventing severe allergic reactions.

A severe allergic reaction, otherwise known as anaphylaxis, is overwhelming and life-threatening.

It affects the whole body or usually several parts of the body.

In particular:

- heart and blood circulation
 - o This may cause, for example, low blood pressure and collapse, or abnormal heartbeat or function.
- air passages and lungs
 - o This causes difficulty in breathing, with noisy wheezing or gasping, possibly with sneezing and a very runny nose.
- stomach and bowels
 - o This may cause nausea, vomiting, diarrhoea and abdominal cramps, often severe.
- skin (very common)
 - o This causes flushing, itching, skin rash, hives or swelling, which may be widespread or in one part of the body.
- brain
 - o There may be fits or confusion due to lack of oxygen.

It is important to act quickly to treat a severe allergic reaction.

EPIPEN:

- provides convenient first-aid
- may be self-administered or administered by a carer
- has a spring-activated, hidden needle
- automatically injects one pre-measured dose of adrenaline
- is for single use only.

If you have any questions about this, talk to your doctor or pharmacist.

2. What should I know before I use EPIPEN?

The EPIPEN Auto-Injector is simple to use. Please read and follow the step-by-step instructions.

Do not remove the blue safety release until you need to use EPIPEN and are ready to use it. The safety release stops EPIPEN from “firing” or working.

Warnings

EPIPEN is a life-saving treatment in the emergency management of severe allergic reactions. Therefore, it

should not be withheld from anyone who is considered to need it.

There is no visible needle. This helps overcome fear of injection. The hidden needle is very fine so that the injection does not usually hurt.

The Auto-Injector has a clear viewing window so you can see the contents.

Do not use EPIPEN if:

- the packaging is torn, doesn't look quite right or shows signs of tampering
- the contents:
 - o are cloudy or
 - o are coloured or
 - o contain sediment or
 - o if the viewing window is obscured

These changes indicate that the effectiveness of the drug product may be decreased.

When the viewing window is obscured, the Auto-Injector cannot be used again.

Check your EPIPEN regularly (see Things you should do in Section [5. What should I know while using EPIPEN?](#)).

Help in using EPIPEN

It is important to know how to use an EPIPEN BEFORE a severe allergic reaction causes a medical emergency.

Ask your doctor or pharmacist how you can get an EPIPEN Training Device for practice.

An EPIPEN Training Device is similar to the real EPIPEN. However, the EPIPEN Training Device:

- has NO medicine (adrenaline) and
- has NO needle and
- “fires” quietly and less forcefully
- can be reset and reused.

Ask your doctor or pharmacist to show you how to practice with the EPIPEN Training Device. If you practice using the EPIPEN Training Device, it will help you to learn how to use the real EPIPEN.

It is important to regularly ask your doctor or pharmacist to demonstrate use with an EPIPEN Training Device.

EPIPEN is effective as emergency treatment of a severe allergic reaction ONLY when used according to the directions in this leaflet.

Give WITH CAUTION to those who have

- high blood pressure
- thyroid problems
- high pressure in the eye (narrow-angle glaucoma).

If you have a thick-subcutaneous fat layer, there is a risk of the adrenaline not reaching the muscle tissue resulting in a suboptimal effect. In such individuals there may be a higher likelihood of needing a second injection with an additional EPIPEN.

Take care also when giving EPIPEN to those:

- having an anaesthetic

or who have:

- diabetes
- heart disease
- allergy to EPIPEN
- brain damage.

Check with your doctor or pharmacist if you have:

- heart disease or high blood pressure
- Parkinson's disease
- depression, or are on medication for depression
- thyroid problems, or are on thyroid medication
- diabetes
- high pressure in the eye (narrow angle glaucoma)
- asthma
- ever had an allergic reaction to sodium metabisulfite
- severe kidney problems
- a tumor in your prostate (prostatic adenoma leading to residual urine)
- high calcium levels or low potassium levels in your blood.

Talk to your doctor if you are allergic to sodium metabisulfite or any of the ingredients listed at the end of this leaflet and have not consulted your doctor or specialist beforehand.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with EPIPEN and affect how it works. These include medicines for:

- heart disease (e.g. digitalis (digoxin), quinidine, alpha and beta blocking medicines)
- treatment of Parkinson's disease (e.g. catechol-O-methyl transferase inhibitors or levodopa)
- depression (especially “tricyclic antidepressants” or monoamine oxidase inhibitors)
- thyroid disease (e.g. levothyroxine sodium or thyroid hormones)
- diabetes
- making you breathe more easily, used for asthma (e.g. theophylline)
- use in labour (e.g. oxytocin)
- acting on the nervous system (parasympatholytics)
- treating allergies (antihistamines e.g. diphenhydramine or chlorpheniramine)

- anaesthesia (e.g. halothane, cyclopropane or trichlorethylene).

These medicines may affect how well the adrenaline in EPIPEN works.

People with diabetes should carefully monitor their glucose levels after use of EPIPEN or EPIPEN JR Auto-Injector as adrenaline can affect the amount of insulin made by the body, thus increasing the blood glucose level.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EPIPEN.

4. How do I use EPIPEN?

It is important to know how to use your EPIPEN in an emergency (see Help in using EPIPEN in Section [2. What should I know before I use EPIPEN?](#)).

Follow carefully all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet or on the EPIPEN Auto-Injector, ask your doctor or pharmacist for help.

How much to use

For single use only. EPIPEN Auto-Injector delivers a fixed dose of adrenaline. The EPIPEN Auto-Injector must be replaced immediately after use.

The dose will be decided by your doctor, who will adjust it individually for you.

- **Use in Adults weighing 30 kg or more**

EPIPEN is intended for a person who weighs 30 kg or more and has been assessed by their doctor or pharmacist.

Note:

Selection of the appropriate dosage is determined according to the careful medical assessment, patient's body weight and the severity of their symptoms. The doctor or pharmacist may choose to recommend more or less than this amount.

There may be instances where the doctor or pharmacist will recommend the use of EPIPEN JR in some adults, based on careful medical assessment.

Unless otherwise advised by the doctor or pharmacist, EPIPEN JR Auto-Injector should be used for children who weigh between 15 kg and 30 kg.

If you have any questions about this, talk to your doctor or pharmacist.

When to use EPIPEN

Use EPIPEN immediately if you have signs and symptoms of a severe allergic reaction, as described by your doctor or pharmacist. Symptoms do vary. However, the symptoms are likely to include:

- collapse
- difficulty in breathing

- wheezing
- swelling, especially of the face, lips, tongue or throat
- flushing of the face
- irregular or faint pulse
- vomiting, diarrhoea, stomach cramps
- skin rash, hives
- itching
- in some cases, loss of consciousness.

In case the first administration is not sufficient, you should carry two EPIPEN Auto-Injector pens with you at all times.

How to use EPIPEN

Important Information - Before Use:

- **Before you ever need to use it, fully familiarise yourself with the EPIPEN Auto-Injector, when and how it should be used.**
- It is recommended that your family members, carers, teachers are also instructed in the correct use of the Auto-Injector.
- Grip only the mid-section of the EPIPEN Auto-Injector. Avoid touching either end, except when you remove the blue safety release. The blue safety release stops the EPIPEN from "firing" or working.
- Always point the orange end (which holds the needle) away from any part of any body, except the planned injection site. This is the outer mid-thigh of the person who has the severe allergic reaction.
- **Always hold the leg firmly during injection especially in people who are uncooperative and kick or move during an injection. This will reduce the risk of injection related injuries.**
- Always keep the Auto-Injector away from the face and eyes.
- Never inject the Auto-Injector into the buttock.

Carefully follow the step-by-step directions to make the EPIPEN work properly.

Step 1

Flip open the yellow cap on the protective carry tube.

Carefully tip and slide the EPIPEN Auto-Injector out of the carry tube.

Check the contents of the EPIPEN Auto-Injector through the viewing window. Make sure the solution is clear, colourless and sediment-free.

Check the expiration date located on the side of the Auto-Injector. Replace the Auto-Injector if the expiration date has passed.

Do not take off the blue safety release if you are not preparing for an injection.

- Remember that the Auto-Injector is activated ("triggered", ready to "fire") as soon as you take off the blue safety release.

Note:

- To avoid an accidental injection, never place thumb, fingers or hand over the orange end as this contains the needle. If an accidental injection happens, get medical help right away.

Step 2

Make a fist around the EPIPEN Auto-Injector, with your thumb nearest to the blue safety release (see FIGURE 1).



FIGURE 1

Step 3

Activate the EPIPEN Auto-Injector by removing the blue safety release with your other hand (also shown in FIGURE 1). This “triggers” the EPIPEN. It is now ready to

- “fire” the needle and
- inject the medicine through the needle into the thigh muscle.

After you remove the blue safety release:

- **Do not touch or place thumb, fingers or hand over the orange end as this contains the needle.**
- **Do not “click” on either end of the EPIPEN Auto-Injector.** The Auto-Injector does not work like a retractable ball-point pen.
- **Do not bump the EPIPEN Auto-Injector if you are not preparing for an injection.**

This will help prevent accidental activation of the EPIPEN Auto-Injector prior to use.

Step 4

Hold the EPIPEN Auto-Injector at a 90° angle (right angle) to the outer part of the thigh. Hold the orange end about 5 cm away from the thigh (see FIGURE 2).



FIGURE 2

Step 5

If you are administering the EPIPEN to another person, hold their leg firmly, especially if they are uncooperative.

Push the orange end FIRMLY into the outer mid-thigh until a “click” is heard or felt.

Keep pressing the EPIPEN Auto-Injector firmly against the thigh for approximately **3 seconds** (see FIGURE 3).



FIGURE 3

NOTE: EPIPEN may be used either

- through clothing, as shown in FIGURE 3, or
- directly to the skin.

When you press the orange end of the Auto-Injector firmly against the thigh, the hidden needle “fires”. It injects the measured dose of adrenaline into the thigh muscle.

Step 6

Carefully take the EPIPEN Auto-Injector away from the thigh. The orange needle cover will extend to cover the needle (see FIGURE 4).



FIGURE 4

Check the viewing window - it should now be obscured. If the viewing window is not obscured, repeat steps 2 to 6 above.

Step 7

Seek further medical attention for yourself immediately. Although you have received adrenaline from EPIPEN, you may need more medical treatment.

Either

- **Contact your doctor or**
- **Call an ambulance (telephone 000 in Australia). State that you or your child have had EPIPEN (intramuscular adrenaline) even if symptoms appear to be improving.**

While waiting for the ambulance you should lie down with your feet raised unless this makes you breathless in which case you should sit up. Ask someone to stay with you until the ambulance arrives in case you feel unwell again.

Unconscious patients should be placed on their side in the recovery position.

Step 8

Record the time EPIPEN was given.

Step 9

With severe, persistent allergic reactions, repeat injections with an additional EPIPEN may be necessary. The EPIPEN dose may be repeated every 5 to 15 minutes if symptoms recur or have not subsided. **Two Auto-Injectors should always be carried in case a second dose is required.**

Do not inject more than two sequential doses of EPIPEN unless under medical supervision. An overdose of adrenaline could cause harm.

You or your child will need to go to hospital for observation and further treatment as required. This is because the reaction may happen again at some time later.

Important Information - After Use

- EPIPEN Auto-Injector is a single-use injectable device that delivers a fixed dose of adrenaline.
- The Auto-Injector **cannot be reused**. Do not try to reuse EPIPEN after the Auto-Injector has been activated.
- The correct dose has been administered if the orange needle tip is extended and the viewing window is blocked.
- Do not tamper with the orange needle cover.
- Do not replace the blue safety release.
- After the Auto-Injector has been used, the extended needle cover will not fit back into the carry tube.
- To avoid injury, follow the used EPIPEN disposal instructions below (see When to discard your medicine in Section [5. What should I know while using EPIPEN?](#)).

Additional information about treatment of insect stinging allergy

Use EPIPEN immediately if you have been stung or bitten by the insect and experience the signs and symptoms as described by your doctor or pharmacist.

If the insect's sting is easily accessible, remove the sting with your fingernails. Do not squeeze, pinch or push the sting deeper into the skin. If available, ice packs or sodium bicarbonate soaks may then be applied to the stung area.

Keep warm, calm, and as still as possible.

If you use too much EPIPEN

Because each EPIPEN contains only one dose, overdosage is unlikely. Overdosage may lead to a rise in blood pressure. This may cause bleeding in the brain or fluid in the lung.

If you think that you have used too much EPIPEN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using EPIPEN?

Things you should do

Check the expiry date on your EPIPEN and mark this expiry date on your calendar or diary.

Also note on your calendar or diary to check the contents of your EPIPEN each month. Do this through the viewing window.

Obtain a new EPIPEN immediately when:

- the solution is brown or contains any particles or cloudiness
- the viewing window is obscured. Return it to your doctor or pharmacist for disposal.
- the Auto-Injector has previously been used
- **the Auto-Injector is about to expire.**

The EPIPEN Auto-Injector can be damaged and made unusable if it is mishandled!

EPIPEN is NOT a toy. Keep it out of reach of children.

Things you should not do

- Do not use EPIPEN to treat any other medical conditions including other types of shock unless your doctor tells you to.
- **Do not use EPIPEN in a child who weighs below 15 kg**
 - Talk to your doctor or pharmacist if this is the case so that a careful assessment can be made and the appropriate dose selected based on the child's weight and the life-threatening nature of the reaction(s) for which EPIPEN is being prescribed.
- **Do not use EPIPEN if the solution is brown or contains any particles or cloudiness.**
- **Do not touch the orange end on any person or object while you are taking off the blue safety release and/or after you have taken off the blue safety release.**
- **Do not inject into hands, feet, ears, nose, buttocks, genital area or into a blood vessel.**
- **If this does happen accidentally you must immediately seek medical attention. See Section [6. Are there any side effects?](#)**

Driving or using machines

Your ability to drive and use machines may be affected by the anaphylactic reaction and possible adverse effects to adrenaline.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the effect of adrenaline.

Looking after your medicine

- Always handle the EPIPEN Auto-Injector carefully, so as not to accidentally activate it or make it “fire” or work.
- Keep EPIPEN readily available with the person for whom it is intended.
- Keep EPIPEN in the protective carry tube until required. Protect from light.
- Store below 25°C. Temperature excursions between 15°C to 25°C permitted.
- Do not store EPIPEN in the fridge.

Store EPIPEN in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Extreme temperatures e.g. heat and dampness may cause the Auto-Injector unit to malfunction.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where children cannot accidentally reach it.

When to discard your medicine

After use, do not just throw away the EPIPEN Auto-Injector.

Continue to handle the EPIPEN Auto-Injector safely and with care. Do this even if you think the EPIPEN Auto-Injector has not “triggered”, “fired” or worked properly.

You CANNOT RE-USE the EPIPEN Auto-Injector even though some adrenaline is left inside it.

Give your used EPIPEN to the doctor, pharmacist or to a hospital. This is for inspection, if required, and also for safe disposal. The used EPIPEN should be placed in a rigid sharps disposal unit.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• fast or noticeable heartbeat • difficulty breathing • chest pain • shortness of breath • dizziness	Speak to your doctor if you have any of these less serious side effects and

Less serious side effects	What to do
• flushing or redness of face and skin • pale skin colour • weakness • tremor • headache • throbbing • sweating • nausea or vomiting • sleeplessness • coldness • hallucinations • restlessness • anxiety • fear	they worry you. These side effects are minor and short lasting.

Serious side effects

Serious side effects	What to do
• stroke • lung problems • severe irregular heartbeat • disorientation and impaired memory	More severe side effects can occur occasionally. They are caused by adrenaline stimulating the heart and increasing the blood pressure. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Accidental injection into the hands, fingers or feet may result in the following:

- fast or noticeable heartbeat
- pale skin colour at the site of accidental injection
- feeling of coldness at the site of accidental injection
- bruising or discolouration at the site of accidental injection
- bleeding
- skeletal injury.

If an accidental injection occurs at one of these areas, seek medical attention immediately.

Injection related injuries, such as needle cuts and bent needles, have been reported in people who are uncooperative and kick or move during the injection.

Rare cases of serious skin infections have been reported following injection into the buttock. In case of signs or symptoms of injection site infection, such as swelling, persistent redness, heat (warmth) or pain (tenderness) always seek medical help immediately.

Sodium metabisulfite

EPIPEN contains a very small quantity of sodium metabisulfite as a preservative. In people who are allergic to sodium metabisulfite, this could cause, for example, severe allergic reactions (hypersensitivity) or breathing difficulty (bronchospasm) in certain groups of people, especially those with history of asthma. However, the active ingredient, adrenaline, in EPIPEN is expected to overcome any allergic reaction to sodium metabisulfite. In an emergency, the risk of exposure to the very small amount of sodium metabisulfite is generally outweighed by the benefits of EPIPEN.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available with a doctor's prescription. You can also purchase it directly from a pharmacy.

What EPIPEN contains

Active ingredient (main ingredient)	Adrenaline (epinephrine) 300 micrograms in 0.3 mL
Other ingredients (inactive ingredients)	• sodium chloride • sodium metabisulfite • hydrochloric acid • Water for Injections
Potential allergens	Sulfites

Consult your doctor or specialist if you are allergic to any of these ingredients.

What EPIPEN looks like

EPIPEN delivers one x 0.3 mL dose of adrenaline (epinephrine). This EPIPEN dose provides 300 micrograms of adrenaline (epinephrine) (AUST R 42978).

The EPIPEN Auto-Injector holds 2 mL of adrenaline (epinephrine) 1:1,000 solution.

The EPIPEN Auto-Injector is packed in a non-waterproof protective plastic carry tube. This carry tube has a yellow cap. The carry tube is supplied in a cardboard pack.

Who distributes EPIPEN

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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Made in USA

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