

Oralvac Compact[®] Sublingual Immunotherapy Treatment (SLIT)

Information for patients



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What is Oralvac Compact®?

Oralvac Compact® is a sublingual (under the tongue) once daily treatment that is used in children and adults who have severe allergies to pollens (grass or tree) or to house dust mites. It comes in the form of drops that are placed under the tongue. Oralvac Compact® drops contain a tiny amount of either grass or tree pollen or house dust mites. Taken daily Oralvac Compact® can help the immune system develop a tolerance to grass or tree pollen or house dust mites.

Oralvac Compact® is **taken daily for three years**. If the treatment is to be successful and have long-term benefits, it is extremely important that Oralvac Compact® drops are taken every day during the entire treatment period, unless there are troublesome side effects or the person taking Oralvac Compact® is unwell.

When do I start Oralvac Compact®?

The first dose of the immunotherapy will be administered in the Children's Day Unit. You will be sent details of the date, time and place. You/your child will need to stay for approximately one hour after the first dose. During this time, you/your child will be monitored closely for any symptoms or signs of an allergic reaction. After this initial visit, you/your child will continue to take the treatment at home every day.

How do I take Oralvac Compact®?

Oralvac Compact® comes in drops, which are placed under the tongue. The drops need to be held under the tongue for one minute without swallowing. No food or drink is permitted for 5 minutes after taking the Oralvac Compact® drops.

If you are taking any other sublingual immunotherapy medications (e.g. Grazax®) - we recommend you leave at least **ONE HOUR** between different sublingual medications.

Important Points

- Do not exercise for 1 hour before or after taking Oralvac Compact®
- Ensure the mouth is clear of food, rinse mouth if necessary
- Remind/remember to hold the drops under the tongue for 1 minute without swallowing
- Do not eat or drink anything for 5 minutes after the drops.
- Take Oralvac Compact® at the same time every day, ideally in the morning.

When shouldn't Oralvac Compact® be taken?

Oralvac Compact® works by stimulating and altering your immune system through the immune cells found in the lining of your mouth. Oralvac Compact® should be missed on days when the person taking Oralvac Compact® is unwell (as the immune system is already in 'overdrive'), or if the mouth is tender, cut or inflamed.

Oralvac Compact® daily treatment should be temporarily stopped if any of the following occur:

1. Asthma attack
2. Infection/viral illness
3. High temperature
4. Any injury or sores in the mouth (for example - cold sores, tooth removal/loss, trauma to mouth during sports injury).
5. On the day a vaccination is given and whilst experiencing the side effects of a vaccination

How should Oralvac Compact® be restarted after a break or a missed dose?

Oralvac Compact® should be restarted once the acute phase of the illness/infection has passed.

Oralvac Compact® should be restarted after wounds in the mouth have healed or 7 days after tooth extraction.

If a dose is accidentally missed/forgotten - **DO NOT** take a double dose. Resume with the usual daily dose.

If treatment is stopped for **less than 3 days** - return to **usual maintenance dose**.

If the treatment is stopped for **longer than 3 days** please contact the allergy nurses for advice on restarting the Oralvac Compact® treatment

If the treatment has been stopped for **longer than 28 days** then **treatment should be re-started under supervision in the hospital**. Please inform the allergy specialist nurse.

Should other allergy medications be stopped while taking Oralvac Compact® ?

No. Initially the advice is to remain on all the same allergy medications as usual. It may take up to a year from starting Oralvac Compact® to notice an improvement in symptoms.

Over time it is anticipated that you will be able to reduce or stop some or all of the allergy medications.

The allergy team will provide direction on how to reduce regular allergy medications at follow up clinic visits, depending on the severity of allergy symptoms.

Can any new medications be started whilst on Oralvac Compact®?

Please discuss with a member of the allergy team before starting any new medications or having other immunotherapy treatment.

At any time during the treatment period of 3 years, please remember to inform the allergy team of any new medications you/your child are advised to take.

How to store Oralvac Compact®

Keep out of reach and sight of children.

Store Oralvac Compact® upright in a refrigerator (2°-8°C). Do not freeze.

After opening a bottle, **it can be left for up to 10 weeks outside a refrigerator**, as long as it is kept at room temperature (not above 25°C).

Repeat prescriptions

Oralvac Compact® is ordered individually for patients, and can only be supplied by the pharmacy at the Leeds General Infirmary.

It can take 2-4 weeks to have the next Oralvac Compact® kit delivered.

Please email the allergy nurses as soon as the last bottle in the box has been opened.

If Oralvac Compact® drops are not being taken as prescribed or if clinic appointments are not attended, then the allergy team may discontinue the Oralvac Compact® treatment before the 3 years have completed.

Contact telephone numbers

Children's Allergy Nurse Specialists (Monday to Friday 08:00 - 17:00pm) (0113) 392 2257 or 07789 174 342 or email leedsth-tr.allergy@nhs.net

Paediatric Consultants (Monday to Friday 09:00 - 17:00pm)
Dr Aida Semic-Jusufagic / Dr Hodge (0113) 392 2840
(secretary's desk)

Out of hours: Phone the hospital switchboard and ask for the Paediatric Medical registrar on-call

Main hospital switchboard: (0113) 243 2799

What are the possible risks of Oralvac Compact® treatment?

Sublingual immunotherapy is very safe. Large studies on hundreds of children have never found any serious reactions. The most common side effects were itchiness and swelling in the mouth, or mild allergy symptoms for example a runny nose or watery eyes after taking the Oralvac Compact® drops. These tend to happen immediately after administration of the Oralvac Compact® drops and usually do not last longer than then 10-15 minutes. Itch and tingling can be managed by taking an antihistamine 20-30 min before taking the Oralvac Compact® drops.

These symptoms usually subside once the body gets used to the treatment, within 2 weeks. However, if they persist or are troublesome, please contact the allergy team to discuss this.

Other rarer side effects include headaches, tiredness, swelling of the tongue or lips, itchy hives on skin, eczema flare, sneezing, runny or blocked nose and watery itchy eyes, and abdominal pain. If these occur, take an antihistamine and inform a member of the allergy team.

Important - If your child develops begins to experience difficulty in swallowing particularly when eating food (feeling like the food is 'stuck' in their throat) or needs to wash food down with fluids, or experiences heartburn or vomiting - please inform the allergy team immediately. This can be a sign of a rare complication of sublingual immunotherapy called Eosinophilic Oesophagitis.

If any severe or worrying side effects are experienced - please do not give your child any further Oralvac Compact® drops until you have discussed your concerns with the Children's Allergy team.

If any of the following symptoms occur following a Oralvac Compact® dose, please follow the treatment plan below.

Make sure antihistamine medication is always available.

General guidance on how to manage delayed reactions:

Reaction	What to do
<ul style="list-style-type: none">• skin rash, swelling or redness at site of injection, if troublesome	<ul style="list-style-type: none">• Take 1 dose of cetirizine or other non-sedating antihistamine, as advised.
<ul style="list-style-type: none">• mild shortness of breath• mild chest tightness• mild cough• mild wheeze or whistling in chest	<ul style="list-style-type: none">• take 2-4 puffs of reliever (blue) inhaler, if prescribed.
<ul style="list-style-type: none">• mild throat irritation, itching or tightness	<ul style="list-style-type: none">• Take 1 dose of cetirizine or other non-sedating antihistamine, as advised.
<ul style="list-style-type: none">• generalised skin rash or hives• swelling of lips, tongue, face or other location (not causing shortness of breath)	<ul style="list-style-type: none">• Take 1 dose of cetirizine or other non-sedating antihistamine as advised. This dose can be repeated after 30 minutes if no improvement in rash or swelling.

Reaction	What to do:
<ul style="list-style-type: none"> • Severe systemic reactions (any or all of the symptoms below): • severe shortness of breath • severe chest tightness • severe cough • severe wheeze or whistling in chest • severe throat tightness causing difficulty breathing or voice hoarseness • light-headedness, dizziness, blurred vision - suggestive of a drop in blood pressure 	<p>Call 999</p> <ul style="list-style-type: none"> • if you have already been prescribed an adrenaline auto-injector, self-administer it as directed • take a double dose of cetirizine or other non-sedating antihistamine as advised • take 4-10 puffs of reliever (blue) inhaler, if prescribed

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