

Package leaflet: Information for the patient

Norsed Combi D 35 mg + 1000 mg / 880 IU film-coated tablets + effervescent granules
Risedronate sodium + calcium / colecalciferol

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.

What is in this leaflet

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

1. What Norsed Combi D is and what it is used for

What Norsed Combi D is

A combination medicine packed as weekly units each containing 1 tablet of Norsed and 6 sachets of calcium/vitamin D3.

○ *Norsed tablets*

Norsed tablets contain risedronate sodium which belongs to a group of non-hormonal medicines called bisphosphonates. These medicines are used to treat bone diseases. It works directly on your bones to make them stronger and therefore less likely to break.

Bone is a living tissue. Old bone is constantly removed from your skeleton and replaced with new bone.

Postmenopausal osteoporosis is a condition occurring in women after the menopause where the bones become weaker, more fragile and more likely to break after a fall or strain.

The spine, hip and wrist are the most likely bones to break, although this can happen to any bone in your body. Osteoporosis-related fractures can also cause back pain, height loss and a curved back.

Many patients with osteoporosis have no symptoms and you may not even have known that you had it.

□ *Calcium/vitamin D3 sachets*

The sachets contain calcium/vitamin D3 effervescent granules which provide the calcium and the vitamin D3 that your body may need to harden new bone.

What Norsed Combi D is used for

The treatment of osteoporosis, even if severe, in postmenopausal women who also need daily calcium and vitamin D3 supplementation as assessed by their doctor. It reduces the risk of spinal and hip fractures.

2. What you need to know before you take Norsed Combi D

Do not take Norsed Combi D

- If you are allergic to risedronate sodium, calcium carbonate, vitamin D3, peanut or soya or any of the other ingredients of this medicine (listed in section 6)
- If your doctor has told you that you have a condition called:
hypocalcaemia (a low blood calcium level),
hypercalcaemia (a high blood calcium level),
hypercalciuria (a high calcium level in the urine),
hypervitaminosis D (a high blood vitamin D level)
- If you may be pregnant, are pregnant or planning to become pregnant
- If you are breast-feeding
- If you have severe kidney problems, including kidney stones.

Warnings and precautions

Talk to your doctor or pharmacist before taking Norsed Combi D

- If you are unable to stay in an upright position (sitting or standing) for at least 30 minutes.
- If you have abnormal bone and mineral metabolism (for example lack of vitamin D, parathyroid hormone abnormalities, both leading to a low blood calcium level).
- If you have or have had problems in the past with your oesophagus (the tube that connects your mouth with your stomach). For instance you may have or have had pain or difficulty in swallowing food or you have previously been told that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus).
- If you have been told by your doctor that you have an intolerance to some sugars.
- If you have a condition called sarcoidosis (an immune system disorder mainly affecting the lungs, which causes shortness of breath and cough).
- If you are already taking supplements of vitamin D.
- If you have had or have pain, swelling or numbness of the jaw or a “heavy jaw feeling” or loosening of a tooth.
- If you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Norsed Combi D.

Your doctor will advise you on what to do when taking Norsed Combi D if you have any of the above.

Children and adolescents

Risedronate sodium is not recommended for use in children below 18 due to insufficient data on safety and efficacy.

Other medicines and Norsed Combi D

☐ Norsed tablets

Medicines containing one of the following lessen the effect of the Norsed tablet if taken at the same time:

- calcium
- magnesium
- aluminium (for example some indigestion mixtures)
- iron.

Take these medicines at least 30 minutes after your Norsed tablet.

☐ Calcium/vitamin D3 sachets

Medicines containing calcium/vitamin D3 are known to interfere with the following:

- digitalis (used to treat heart disorders)
- tetracycline antibiotics
- steroids (such as cortisone)
- sodium fluoride (used to strengthen the tooth enamel)
- thiazide diuretics (used to remove water from the body by increasing urine production)

- cholestyramine (used to treat high blood cholesterol levels)
- laxatives (such as paraffin oil).

If you are taking any of the above-mentioned medicines, your doctor will give you further instructions.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Norsed Combi D with food and drink

○ Norsed tablets

It is very important that you do NOT take your Norsed tablet with food or drinks (other than plain water) so that it can work properly. In particular do not take the tablet at the same time as dairy products (such as milk) as they contain calcium (see section 2, “Other medicines and Norsed Combi D”).

Take food and drinks (other than plain water) at least 30 minutes after your Norsed tablet.

□ Calcium/vitamin D₃ sachets

Do NOT take the dissolved calcium/vitamin D₃ granules at the same time as foods containing high amounts of oxalic acid (spinach and rhubarb) or phytic acid (whole cereals).

Take the dissolved granules at least 2 hours after eating such foods.

Pregnancy and breast-feeding

Do NOT take Norsed Combi D if you are pregnant, think you may be pregnant or planning to have a baby (see section 2, “Do not take Norsed Combi D”). The potential risk associated with the use of risedronate sodium (active substance in Norsed tablets) in pregnant women is unknown.

Do NOT take Norsed Combi D if you are breast-feeding (see section 2, “Do not take Norsed Combi D”).

Driving and using machines

Norsed Combi D is not known to affect your ability to drive and use machines.

○ Norsed tablets

Norsed tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Norsed tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

□ Calcium/vitamin D₃ sachets

The effervescent granules contain sorbitol

Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

The effervescent granules contain sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

The effervescent granules contain soya-bean oil

If you are allergic to peanut or soya, do not use this medicinal product (see section 2, “Warnings and precautions” and “Do not take Norsed Combi D”).

The calcium/vitamin D3 granules contain potassium (163 mg per sachet). This should be taken into consideration if you have a reduced kidney function or are on a controlled potassium diet.

The effervescent granules contain sodium

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

3. How to take Norsed Combi D

Norsed Combi D is a weekly therapy presented in a box containing 1 tablet (in a blister) and 6 sachets containing effervescent granules that should be taken in a special way. Every weekly box has dosing instructions on the back.

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

Recommended dose:

Weekly cycle:

- *Day 1: Norsed tablet (light-orange tablet)*
Take ONE Norsed tablet once a week.
Choose one day of the week that best fits your schedule. This will be your Day 1 of the weekly cycle. Every week, take the Norsed tablet on your chosen Day 1.
- *Days 2 to 7: Calcium/vitamin D3 sachets (effervescent granules)*
Beginning on the day after the Norsed tablet has been taken,
Take ONE sachet of calcium/vitamin D3 granules each day for the next 6 days.

Every 7 days start a new weekly box. You should begin a new box by taking the Norsed tablet on your chosen Day 1.

Do NOT take your Norsed tablet and the sachet on the same day.

WHEN to take the Norsed tablet

Take your Norsed tablet at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

HOW to take Norsed Combi D

☐ Norsed tablets

- Take the tablet whilst you are in an upright position (you may sit or stand) to avoid heartburn.
- Swallow it with at least one glass (120 ml) of plain water.
- Swallow it whole. Do not suck or chew it.
- Do not lie down for 30 minutes after taking your tablet.

☐ Calcium/vitamin D3 sachets

Pour the content of the sachet into a glass of plain water and stir. Wait until the fizzing has subsided, then drink the solution.

If you take more Norsed Combi D than you should

☐ Norsed tablets

If you have taken more tablets than you should, or if children have been taking medicine by accident, drink one full glass of milk and seek medical attention.

☐ Calcium/vitamin D3 sachets

If you have taken more **sachets** than you should, or if children have been taking medicine by accident, please contact your doctor.

If you forget to take Norsed Combi D

☐ Norsed tablets

If you have forgotten to take your tablet on your chosen day (Day 1):

1. Take it on the day you remember. Do NOT take two tablets in one day to make up for the tablet you missed.
2. On the following day take your calcium/vitamin D3 sachet. Do NOT take your Norsed tablet and the sachet on the same day.
3. Continue taking one sachet each day until the end of the weekly cycle.
4. Discard any remaining sachets in the box at the end of the weekly cycle.

Then start a new weekly cycle: take one Norsed tablet once a week on your chosen Day 1.

☐ Calcium/vitamin D3 sachets

If you have forgotten to take a calcium/vitamin D3 sachet:

1. Take it on the day you remember. Do NOT take the sachet on the same day as the Norsed tablet. Do NOT take two sachets on the same day.
2. Continue taking one sachet each day until the end of the weekly cycle.
3. Discard any remaining sachets in the box at the end of the weekly cycle.

If you stop taking Norsed Combi D

If you stop treatment you may begin to lose bone mass. Please talk to your doctor before you consider stopping treatment.

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.

☐ Norsed tablets

Stop taking Norsed and contact a doctor immediately if you experience any of the following:

- Symptoms of a severe allergic reaction such as;
 - Swelling of face, tongue or throat
 - Difficulties in swallowing
 - Hives and difficulties in breathing
- Severe skin reactions that can include blistering of the skin.

Tell your doctor promptly if you experience the following side effects:

- Eye inflammation, usually with pain, redness and light sensitivity.
- Bone necrosis of the jaw (osteonecrosis) associated with delayed healing and infection, often following tooth extraction (see section 2, "Warnings and precautions").
- Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or worsened heartburn.

Unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.

However in clinical studies the other side effects that were observed were usually mild and did not cause the patient to stop taking their tablets.

Common side effects (may affect up to 1 in 10 people)

- Indigestion, feeling sick, stomach ache, stomach cramps or discomfort, constipation, feelings of fullness, bloating, diarrhoea.
- Pain in your bones, muscles or joints.
- Headache.

Uncommon side effects (may affect up to 1 in 100 people)

- Inflammation or ulcer of the oesophagus (the tube that connects your mouth with your stomach) causing difficulty and pain in swallowing (see also section 2, “Warnings and precautions”), inflammation of the stomach and duodenum (bowel draining the stomach).
- Inflammation of the coloured part of the eye (iris) (red painful eyes with a possible change in vision).

Rare side effects (may affect up to 1 in 1,000 people)

- Inflammation of the tongue (red swollen, possibly painful), narrowing of the oesophagus (the tube that connects your mouth with your stomach).
- Abnormal liver tests have been reported. These can only be diagnosed from a blood test.

During post-marketing experience, the following have been reported

- Very rare: Talk to your doctor if you have ear pain, discharge from the ear, and/or and ear infection. These could be signs of bone damage in the ear.
- Unknown frequency:
 - Hair loss
 - Liver disorders, some cases were severe.

Rarely, at the beginning of treatment, a patient’s blood calcium and phosphate levels may fall. These changes are usually small and cause no symptoms.

□ Calcium/vitamin D₃ sachets

Uncommon side effects (may affect up to 1 in 100 people)

- Hypercalcaemia (a high blood calcium level, with potential symptoms of excessive thirst, loss of appetite, fatigue and in severe cases irregular heart beat), hypercalciuria (a high calcium level in the urine).

Rare side effects (may affect up to 1 in 1,000 people)

- Constipation, wind, nausea, abdominal pain, diarrhoea.
- Skin reactions such as itching, rash and hives.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#)*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Norsed Combi D

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 cartons after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Norsed Combi D contains

☐ Film-coated tablets

The active substance is risedronate sodium. Each tablet contains 35 mg risedronate sodium, equivalent to 32.5 mg risedronic acid.

The other ingredients are:

Tablet core: lactose monohydrate (see section 2), crospovidone A, magnesium stearate and cellulose microcrystalline.

Film coating: hypromellose, macrogol, hydroxypropylcellulose, colloidal anhydrous silica, titanium dioxide [E171], iron oxide yellow [E172], iron oxide red [E172].

☐ Effervescent granules sachets

The active substances are calcium carbonate and colecalciferol (vitamin D₃). Each sachet of effervescent granules contains 1000 mg calcium (as 2500 mg calcium carbonate) and 22 micrograms (880 International Units [IU]) of colecalciferol (vitamin D₃).

The other ingredients are: citric acid anhydrous, malic acid, gluconolactone, maltodextrin, sodium cyclamate, saccharin sodium, sorbitol [E420], mannitol [E421], dextrin, acacia, natural lemon oils, natural lime flavour, rice starch, potassium carbonate, all-rac- α -tocopherol, soya-bean oil (hydrogenated), gelatin, sucrose, maize starch.

What Norsed Combi D looks like and contents of the pack

The combination pack is constituted of an outer carton pack containing weekly unit(s) (carton boxes). Each weekly unit contains:

- one film-coated tablet which is an oval light-orange tablet with the letters “RSN” on one side and “35 mg” on the other side, packaged in a blister card.
- 6 sachets of effervescent granules of calcium and vitamin D₃.

Pack sizes: 1, 2, 4, 12 (3x4) and 16 (4x4) weekly units.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

[to be completed nationally]

Manufacturer:

Hermes Pharma GmbH
Schwimmschulweg 1a
A-9400 Wolfsberg
Austria

This medicine is authorised in the Member States of the EEA under the following names: Ireland:
Optinate Plus Ca & D 35 mg film-coated tablets + 1000 mg / 880 i.u. effervescent granules Sweden:
Norsed Combi D 35 mg + 1000 mg / 880 IE filmdragerade tabletter + brusgranulat

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