



SELECT THE REQUIRED INFORMATION



PROFESSIONAL INFORMATION



PATIENT INFORMATION LEAFLET

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Complementary Medicine: **Health Supplement**
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

BEROCCA® EXPERT Vit D Tablets
Vitamin K2, Vitamin D3 and Calcium
Sugar free

Read all of this leaflet carefully because it contains important information for you

Berocca® Expert Vit D Tablets is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Berocca® Expert Vit D Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Berocca® Expert Vit D Tablets with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet?

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

1. What Berocca® Expert Vit D Tablets is and what it is used for

Berocca® Expert Vit D is a triple layer tablet containing vitamin D, vitamin K and calcium. Berocca® Expert Vit D Tablets intake, when combined with a healthy diet and regular exercise,

- May reduce the risk of developing osteoporosis,
- Contributes to the development and maintenance of bones and teeth, and
- Is a factor in the maintenance of good health.

2. What you need to know before you take Berocca® Expert Vit D Tablets**Do not take Berocca® Expert Vit D Tablets:**

- If you are hypersensitive (allergic) to any of the other ingredients of Berocca® Expert Vit D Tablets (listed in section 6).
- If you already have too much vitamin D in your body, you shouldn't use this product.
- If you already have too much calcium in your blood (hypercalcaemia), a history of kidney stones (nephrolithiasis), or too much oxalate in their urine (hyperoxaluria) you should avoid this product.

Warnings and precautions

Don't exceed the recommended dose. Overdosing can lead to harmful effects. Special care should be taken with Berocca® Expert Vit D Tablets:

- If you're already taking other vitamins, medications, or if you're under medical care, you should talk to a healthcare professional before using this product.
- If you're taking medicines similar to vitamin D, you should avoid this product to prevent having too much vitamin D or calcium in your body. If you must take them together, you need to regularly check your blood and urine for calcium levels.
- Patients on vitamin K antagonists or other anticoagulation treatments should consult a healthcare professional before using Berocca® Expert Vit D Tablets.
- If you suffer from kidney stones or urinary stones you should be cautious when using vitamin supplements, such as calcium, and vitamin D may affect stone formation.
- When taking this product, make sure to take it at least four hours apart from other medications unless otherwise specified.

Other medicines and Berocca Expert Vit D

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

Active Ingredient	Drug	Description
Vitamin K	Warfarin (blood thinning medicine)	Very high dietary (>150 µg/day) or supplemental intake of vitamin K may compromise the anticoagulant effect of warfarin. It is recommended to avoid fluctuation in vitamin K intake that might interfere with the adjustment of their anticoagulant dose.
	Vitamin D analogues (e.g. Calcitriol)	Concomitant treatment with vitamin D analogues should be avoided due to increased risk of hypervitaminosis D and/or hypercalcaemia. Vitamin D analogues include ergocalciferol and calcitriol. If deemed essential, serum and urine calcium levels should be monitored.
	Cholestyramine (cholesterol lowering medication)	Gastro-intestinal absorption of vitamin D is decreased with simultaneous administration. Separate intake of the product and these medications by four hours, unless otherwise specified, will minimize risk for any interaction.
	Thiazide diuretics (e.g. Bendroflumethiazide)	Thiazide diuretics (e.g., Hygroton®, Lozol®, and Microzide®) decrease urinary calcium excretion. The combination of these diuretics with vitamin D supplements (which increase intestinal calcium absorption) might lead to hypercalcemia, especially among older adults and individuals with compromised renal function or hyperparathyroidism.
Vitamin D3	Vitamin D analogues (e.g. Calcitriol)	Concomitant treatment with vitamin D analogues should be avoided due to increased risk of hypervitaminosis D and/or hypercalcaemia. Vitamin D analogues include ergocalciferol and calcitriol. If deemed essential, serum and urine calcium levels should be monitored.

Active Ingredient	Drug	Description
	Cholestyramine (cholesterol lowering medication)	Gastro-intestinal absorption of vitamin D is decreased with simultaneous administration. Separate intake of the product and these medications by four hours, unless otherwise specified, will minimize risk for any interaction.
	Thiazide diuretics (e.g. Bendroflumethiazide)	Thiazide diuretics (e.g., Hygroton®, Lozol®, and Microzide®) decrease urinary calcium excretion. The combination of these diuretics with vitamin D supplements (which increase intestinal calcium absorption) might lead to hypercalcemia, especially among older adults and individuals with compromised renal function or hyperparathyroidism.
Calcium	Tetracycline antibiotics	As a polyvalent cation; calcium forms complexes with certain substances resulting in decreased absorption of both substances. Separate intake of the product and these medications by 4 hours, unless otherwise specified, will minimize risk for this interaction.
	Quinolone antibiotics	
	Lithium	
	Levothyroxine	
	Dolutegravir (antiviral medicine)	

Berocca® Expert Vit D Tablets with food

Allowance should be made for intake of the vitamins and minerals from all other sources including fortified foods.

Oxalic acid (in spinach and rhubarb) and phytic acid (in fiber-rich whole grains) can interfere with your body's ability to absorb calcium. If you're taking Berocca® Expert Vit D Tablets avoid eating foods high in these substances within two hours of taking it to ensure better calcium absorption.

Pregnancy and breastfeeding

Berocca® Expert Vit D Tablets is not intended for use during pregnancy and lactation.

Driving and using machines

The product has no or negligible influence on the ability to drive and use machines.

3. How to take Berocca® Expert Vit D Tablets

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

Always take Berocca® Expert Vit D Tablets exactly as described in this leaflet or as your doctor, or pharmacist has told you. Check with your doctor or, pharmacist if you are not sure.

The usual dose for adults is one tablet a day taken by mouth with water.

If you take more Berocca® Expert Vit D Tablets 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 take too much of this product, you might suddenly get a headache, feel confused, or have stomach problems like constipation, diarrhoea, feeling sick, or throwing up. If you notice any of these things, stop using the product right away and get in touch with a doctor or nurse.

Taking too much of this product over a short or long period of time can lead to an overload of vitamins D in your body.

The specific signs that you've taken too much can vary a lot. They depend on things such as how your body reacts and your given circumstances. So, it's important to pay attention to how you're feeling and get medical help if you think you've taken too much.

If you forget to take Berocca® Expert Vit D Tablets

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

If you stop taking Berocca® Expert Vit D Tablets

Berocca® Expert Vit D Tablets have no withdrawal symptoms or effects should you stop, or interrupt, or end treatment early.

4. Possible side effects

Berocca® Expert Vit D Tablets can have side effects.

Not all side effects reported for Berocca® Expert Vit D Tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Berocca® Expert Vit D Tablets, please consult your health care provider for advice.

If any of the following happens, stop taking Berocca® Expert Vit D Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Berocca® Expert Vit D Tablets. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Blood in the urine or pain with urination,

These are all serious side effects. You may have hypercalciuria and may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Nausea,
- Abdominal discomfort,
- Diarrhoea,
- and vomiting.

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 SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Alternatively, you can report to Bayer SafeTrack site (<https://www.safetrack->

public.bayer.com). By reporting side effects, you can help provide more information on the safety of Berocca® Expert Vit D Tablets.

5. How to store Berocca® Expert Vit D Tablets

Store all medicines out of reach of children.

Store at or below 25 °C.

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

Do not dispose of unused medicines in drains or sewerage (e.g. toilets).

6. Contents of the pack and other information

What Berocca® Expert Vit D Tablets contains:

- The active substances are Vitamin K2 (menaquinone) 44 µg; vitamin D3 (cholecalciferol) 25 µg; and calcium (calcium carbonate) 500 mg.
- The other ingredients are: Microcrystalline cellulose, hydroxypropyl methylcellulose, glycerin monostearate GMS, sodium croscarmellose, magnesium stearate, silicon dioxide, iron oxide brown, and iron oxide yellow.

What Berocca® Expert Vit D Tablets looks like and contents of the pack

Berocca® Expert Vit D Tablets are yellow, white and red oblong layer tablets packed in PVDC/PVC blister tray sealed with aluminium foil. Each tray contains 30 tablets.

Each tray is packed in a printed carton (folding carton), possibly with a leaflet enclosed.

Holder of Certificate of Registration

Bayer (Pty) Ltd.
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Waterfall City
Midrand, 2090
South Africa
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Registration number(s)

To be confirmed upon registration.

Access to the corresponding Professional Information

The corresponding professional information, as well as patient information leaflet in other language(s), may be obtained electronically on the following web address: <https://www.bayer.co.za>.

Manufacturer:
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