

Patient Product Information

FOSTEUM™

genistein aglycone 27 mg

citratated zinc bisglycinate 20 mg

cholecalciferol (vitamin D₃) 200 IU

The Surgeon General's Report (2004) says that half of all women over 50 will break a bone because of osteoporosis. Osteoporosis doesn't hurt until after you break bones, so it's important for you to take charge before that happens. Osteoporosis can be avoided or slowed down with lifestyle changes and therapy. It is important to understand the changes you can make and the product your doctor has prescribed for you to manage your bone loss and help build new bone.

Fosteum™ is a specially formulated prescription medical food product, consisting primarily of a proprietary blend of genistein aglycone (**from soy**) with citratated zinc bisglycinate and vitamin D, for the clinical dietary management of the metabolic processes associated with osteopenia and osteoporosis. **Fosteum** is indicated when a healthy diet and supplements such as calcium plus vitamin D are not enough, but you are not ready for drugs.

Osteopenia and Osteoporosis

Osteopenia and osteoporosis are grades of the same condition. Osteopenia refers to early bone loss. Osteopenia may eventually progress to osteoporosis, which is a condition in which bones become thin enough to break easily. Most people think of their bones as being solid, but bone is actually a living tissue, and is always changing. Your body keeps your bones healthy by continuously replacing old bone with new bone. Osteoporosis is the result of old bone being broken down and less new bone being made than is needed. Osteoporosis may result in fractures (broken bones), especially of the spine, hip and wrist.

Women have the greatest quantity of bone (bone mass) during their late teens or early twenties. Exercise and proper diet aid in forming good bone when you are young. Healthy bone is regularly broken down and replaced; this is a normal process called 'bone turnover'. Estrogen keeps the bone turnover in balance so that the bone remains strong. After about the age of 30, the estrogen levels in a woman's body begin to decrease and at perimenopause (start of the "change"), a woman begins to produce significantly less estrogen. Less estrogen causes more breakdown and less replacement of bone. Over time, these hormonal changes can result in a loss of bone. By the time a woman reaches 65, it is common to have lost 25-30% or more of total bone tissue. This continuing loss of bone may result in fractures. When these fractures occur in the spinal bones (vertebrae), the person can lose height and eventually develop a 'dowager's hump'. Fractures can result in significant pain and disability. Importantly, a person over the age of 50 who has a hip fracture stands a 20% chance of dying in the following year, and most people who suffer hip fractures require living assistance and lose their independence.

Lifestyle Changes

- If you smoke, stop.
- Exercise – even 30 minutes a day broken into 10 minute segments will help strengthen bone. Exercise can be walking, dancing or lifting weights. Even one pound weights will help.
- Do not drink more than one alcoholic beverage a day.
- Make sure you get enough calcium and vitamin D. See the recommended daily intake table below.
- If you are underweight, try to gain to your optimal weight.

How Fosteum Works

Fosteum is the only product available with this amount of genistein aglycone (purified from soy), combined with citratated zinc bisglycinate (a special form of zinc that is absorbed more easily than other forms of zinc) and vitamin D (vitamin D is necessary to absorb calcium and put the calcium into bone). It is not possible to obtain the same level of genistein aglycone from soy foods like tofu or soy milk. This special combination is designed to work safely to help balance bone turnover by slowing down the bone breakdown activity and speeding up the bone building activity. This improves the strength of the bone over time. Improved bone strength may reduce the risk of fracture.

Ingredients

Fosteum contains **genistein aglycone**, which is a part of **soy**. Extended studies in women showed that this genistein produces gain in bone, with no negative effects on the breast or uterus. Studies have also shown that genistein aglycone helps to safely re-balance the breakdown and formation activities in bone without the negative effects that may occur with hormone therapy (HRT).

Zinc is a mineral required for bone, muscle and many other functions in the body. Zinc is added to **Fosteum** because studies have shown that adding zinc to genistein makes the genistein work even better. The special form of zinc in **Fosteum** is easier for the body to absorb than other forms.

Vitamin D is required for strong bones. It helps the body absorb calcium and deposit that calcium in the bone.

Fosteum contains the following other ingredients: dicalcium malate, magnesium stearate, microcrystalline cellulose and magnesium oxide. The capsule is made of vegetable material, and the lettering on the capsule is FD&C Blue #2. **Fosteum** does not contain fructose, glucose, sucrose, lactose, maltodextrin, gluten, tree nuts, peanuts, flavors, or products of animal or seafood origin. The soybeans used to isolate the genistein aglycone in **Fosteum** are organic and not genetically modified. **Fosteum** is Kosher and suitable for vegans.

All the ingredients in **Fosteum** are **GRAS**. This means “**Generally Recognized As Safe**” and is a strict FDA safety standard that all food-based products must meet.

Caution

Do not take **Fosteum** if you are allergic to any ingredient in the product. **Fosteum** is **not** intended for pediatric patients or for pregnant or nursing women because it has not been tested in these groups. Do not take **Fosteum** if you have or have had cancer of the breast or reproductive organs. Make sure that your doctor knows if you have a family history of these cancers. **Fosteum** is not intended for use if you are taking HRT or certain other drugs for osteoporosis. Make sure that your doctor knows all the medications that you are taking.

How to Take Fosteum

Fosteum should be taken twice each day, approximately 12 hours apart. You can take **Fosteum** with or without food. You can take it with any beverage you like, even grapefruit juice or coffee. You do **not** have to sit or stand after taking **Fosteum**. You may take **Fosteum** and lie down immediately if you wish. Since the body cannot absorb more than 500 mg of calcium at a time, you should take calcium in divided doses during the day to get a sufficient amount. Take a calcium or calcium with vitamin D supplement with each capsule of **Fosteum** in order to consume the recommended daily intake of calcium and vitamin D listed in the chart below, or an amount directed by your physician. Each capsule of **Fosteum** contains 200 IU of vitamin D.

Adult Age	Calcium	Vitamin D
19-50	1000 mg	200 IU
51-70	1200 mg	400 IU
>70	1200 mg	600 IU

Side Effects

Fosteum has been shown to reduce the number and intensity of hot flashes and night sweats in the majority of women over time. A small percentage of patients will have nausea or an upset stomach after taking **Fosteum**. If this should happen, try taking **Fosteum** with food. This may reduce the likelihood of nausea or upset stomach. Constipation is also a possible side effect. A small number of patients may experience mild breast tenderness, which usually disappears with time.

Fosteum has been developed, manufactured and labeled in accordance with all applicable federal and state laws and regulations. **Fosteum** is an FDA-regulated, prescription-only product, which is to be used under the supervision of your physician.

If you need more information about Fosteum, ask your doctor or pharmacist for the package insert, which is written for health care professionals, or go to www.fosteum.com .

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