**Composition**
Active substance:
Ossein Hydroxyapatite Compound (OHC).
Excipients: excipients pro compresse ob ducto.

**Pharmaceutical form and quantity of active substance per unit**
One film-coated tablet contains 830 mg of OHC from femur and humerus calf bos taurus species under 6 months old, equivalent to 75 mg of peptide/non collagenic proteinous and 216 mg of collagen (equivalent to about 291 mg of ossein), 178 mg of calcium and 82 mg of phosphorus (equivalent to about 444 mg of hydroxyapatite).

**Indications/ Possibility Usages**
Osteoporosis from various origins.
It may be used to regulate the calcium/phosphorus imbalance in pregnancy and lactation and also in adjunction treatment in fracture healing.

**Posology /Method of administration**
Osteoporosis
Adults: twice a day 2 to 4 film-coated tablets.

Other indications
Adults: 1 to 2 film-coated tablets per day.
Use and security usage of Ossopan®800 have not been systematically studied in children until now.
Ossopan®800 has to be taken with a small amount of liquids.

**Contraindications**
Known hypersensitivity to any constituent of the product, hypercalcaemia, serious hypercalciuria.
Patients suffering from severe renal failure and haemodialysis patients

**Special warnings**
Posology of patients prone to the formation of urinary calculi containing calcium will be at the discretion of the doctor.
Long-term use of high doses of the product is not recommended in patients with renal impairment.

In patients suffering from moderate renal failure, monitoring of serum phosphorus level is recommended.

**Interactions**
Resorption of iron and tetracycline is reduced in vivo with Ossopan®800 due to complex difficult to be resorbed. It is advisable, in such cases, to administer Ossopan®800 nearly 4 hours after the first preparation.
Calcium resorption is increased by concomitantly administration of vitamin D, that is why hypercalcaemia risk has to be evaluated with vitamin D preparations.
Thiazidics diuretics decrease renal elimination of calcium. In case of concomitant administration of Ossopan®800 and thiazidics diuretics, hypercalcaemia risk has to be evaluated.

**Pregnancy and lactation**
Controlled clinical studies in females have not shown any risk for the foetus during the first gestation quarter, there is none significant proof during the following quarters and possibility of a foetal damage is improbable. Ossopan®800 may be used during pregnancy and lactation.

**Possibility of lowered reactions when driving or operating machines**
Not relevant.

**Undesirable effects**
Hypercalcaemia and hypercalciuria when long-term use of high doses.
Abdominal pain, constipation, nausea.
Pruritus), rash.

**Overdose**
None risk of overdosage has been notified.

**Properties/Effects**
Code ATC: A12CX

**Pharmacodynamic properties**
Ossopan®800 contains organic components of the
bone mass and microcrystalline hydroxyapatite in their natural balance. A regulator effect on the bone metabolism has been proven in vitro. The animal experimentation has shown the activation of the remodelling bone. From a clinical point of view, the resorption of calcium (bone mineralization) is higher than with the only administration of calcium salts.

**Pharmacokinetic properties**
None data are available.

**Preclinical product safety data**
There are none preclinical data specific to this product.

Miscellaneous comments
Ossopan®800 contains only trace salts (sodium chloride) and therefore is suitable also for long-term use by patients with high blood pressure.

*Incompatibilities*
Not relevant.

*Influence on diagnostic methods*
Not known.

**Stability**
Ossopan®800 may not be used over the expiration date printed on the packaging under “EXP”.

*Comments about the storage*
Store in a dry room at ambient temperature (between 15°C and 25°C) and out of children’s reach.

*Stamp*
45386 (Swissmedic).

**MARKETING AUTHORITY HOLDER**

**DATE OF LAST REVISION OF THE TEXT**
2014