

## PROFESSIONAL INFORMATION

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

### SCHEDULING STATUS: S0

#### 1. NAME OF THE MEDICINE: OSTERA

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Serving Size	1 Tablet	
Servings Per Container:	60 pack size	60
Vitamin D (as cholecalciferol)		500 IU
Vitamin K (as phytonadione)		500 mcg
Berberine HCl (Phellodendron amurense bark extract)		90 mg
Reduced Iso-Alpha Acids Complex (from hops extract, Humulus lupulus L.)		370 mg

Other Ingredients: Microcrystalline cellulose, stearic acid (vegetable), croscarmellose sodium, calcium silicate, silica, and coating (hypromellose, medium-chain triglycerides, and hydroxypropylcellulose).

#### For full list of excipients, see section 6.1

This product is non-GMO and gluten-free.

#### 3. PHARMACEUTICAL FORM

Yellow, mottled, coated tablet

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

**Ostera** features selective kinase response modulators (SKRMs) in the form of RIAA, berberine, and vitamins D and K to help nutritionally support healthy bone remodelling during the aging process. \*

\* This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. **Ostera** does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product.

##### 4.2 Posology and method of administration

Take one tablet twice daily, or as directed by your healthcare practitioner.

##### 4.3 Contraindications

None known

##### 4.4 Special warnings and precautions for use

If pregnant, nursing, or taking medication, consult your healthcare practitioner before use  
Keep out of the reach of children.

##### 4.5 Interaction with other medicines and other forms of interaction

None known.

##### 4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of **Ostera** in pregnant or breast-feeding woman.

##### 4.7 Effects on ability to drive and use machines

There are no adequate data from the use of **Ostera** on the ability to drive and use machines.

##### 4.8 Undesirable effects

None known.

##### 4.9 Overdose

Treatment is symptomatic and supportive.

#### 5. PHARMACOLOGICAL PROPERTIES

##### 5.1 Pharmacodynamic properties

Category of medicine: D (Complementary Medicine)  
Class of medicine: 34.13 Health supplements - Other

##### 5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on **Ostera** product

#### 6. PHARMACEUTICAL PARTICULARS

##### 6.1 List of excipients

Tablet core:  
Microcrystalline cellulose  
Stearic acid (vegetable)  
Croscarmellose sodium  
Calcium silicate  
Silica  
Tablet coating:  
Hypromellose  
Medium-chain triglycerides  
Hydroxypropylcellulose

##### 6.2 Incompatibilities

None known.

##### 6.3 Shelf Life

24 Months.

##### 6.4 Special precautions for storage

Keep tightly closed in a cool, dry place  
Keep tablets in original container until required for use.  
KEEP OUT OF REACH OF CHILDREN.

##### 6.5 Nature and contents of container

Packs of 60 tablets in amber glass bottles.  
Pack-size: 60 tablets.

##### 6.6 Special precautions for disposal

No special requirements.

#### 7. HOLDER OF CERTIFICATE OF REGISTRATION

Amipro Advanced Development Products (pty) Ltd  
Unit 3 Eastgate Business Park, 1 South Road, Marlboro, Sandton, Johannesburg 2063  
Tel: 011 802 8101

#### 8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

#### 9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.