

## PATIENT INFORMATION LEAFLET FOR ARTHROSAN PLUS TABLETS

### SCHEDULING STATUS

**S0**

### ARTHROSAN PLUS TABLETS

Glucosamine sulphate (shellfish), methylsulfonylmethane (MSM), chondroitin sulphate (bovine), *lentinus edodes* (shiitake mushroom powder), L-ascorbic acid (vitamin C), manganese glycinate, selenium glycinate.

Contains sweetener: Each tablet contains 290 mg sorbitol (E420).

Contains sugar alcohol: Each tablet contains 140 mg mannitol (E421).

### COMPLEMENTARY MEDICINE: COMBINATION PRODUCT

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

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

ARTHROSAN PLUS TABLETS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use ARTHROSAN PLUS TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.

### What is in this leaflet

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

#### 1. What ARTHROSAN PLUS TABLETS is, and what it is used for

ARTHROSAN PLUS TABLETS contain multiple ingredients to improve and maintain the health of your bones and joints.

#### 2. What you need to know before you take ARTHROSAN PLUS TABLETS

##### Do not take ARTHROSAN PLUS TABLETS:

- if you are under the age of 18 years;
- if you are hypersensitive (allergic) to Glucosamine sulphate (shellfish), methylsulfonylmethane (MSM), chondroitin sulphate (bovine), *lentinus edodes* (shiitake mushroom powder), L-ascorbic acid (vitamin C), manganese glycinate, selenium glycinate or any of the other ingredients of ARTHROSAN PLUS TABLETS (see **What ARTHROSAN PLUS TABLETS contains**);
- if you are taking medication to prevent blood clots (anticoagulants).

### Warnings and precautions

Take special care with ARTHROSAN PLUS TABLETS:

- if you have any problems with your liver;
- if you have asthma;
- if you have prostate cancer, or if this condition is present in your family;
- if you have glaucoma (high pressure in the eyes);
- if you have kidney problems or disease;
- if you are diabetic and you are taking medicines to control your blood sugar levels;
- if you have heart problems or disease;
- If you have a history of non-melanoma skin cancer;
- if you are having any surgical procedure done. You should stop taking ARTHROSAN PLUS TABLETS two weeks before an operation.

### **Other medicines and ARTHROSAN PLUS TABLETS**

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

Tell your doctor or pharmacist if you are currently using:

- anticoagulant medicines (used to prevent your blood from clotting) or herbal supplements with blood thinning effects.

### **ARTHROSAN PLUS TABLETS with food and drink**

See section 3 (**How to take ARTHROSAN PLUS TABLETS**).

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Safety and efficacy of ARTHROSAN PLUS TABLETS during pregnancy and breastfeeding have not been established. Do not use this medicine if you are pregnant or breastfeeding your baby.

### **Driving and using machines**

Safety and efficacy when driving or operating machines have not been established. Do not drive a vehicle, operate machines, or do anything else that requires your attention until you know how ARTHROSAN PLUS TABLETS affects you.

### **ARTHROSAN PLUS TABLETS contains mannitol (E421):**

ARTHROSAN PLUS TABLETS contains mannitol and may cause a mild laxative effect.

### **ARTHROSAN PLUS TABLETS contains sorbitol (E420):**

ARTHROSAN PLUS TABLETS contains sorbitol, which is a source of fructose. If your doctor has told you that you have an intolerance to some sugars, talk to your doctor before you take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and a mild laxative effect.

## **3. How to take ARTHROSAN PLUS TABLETS**

Do not share your medicines with any other person.

Always take ARTHROSAN PLUS 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 is:

*Adults (18 years and older):* Take 3 tablets per day after meals.

If you have the impression that the effect of ARTHROSAN PLUS TABLETS is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

ARTHROSAN PLUS TABLETS is for oral use only and should be swallowed with sufficient liquid.

ARTHROSAN PLUS TABLETS should not be taken at bedtime.

ARTHROSAN PLUS TABLETS should not be taken by children under the age of 18 years.

### **If you take more ARTHROSAN PLUS TABLETS than you should**

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining ARTHROSAN PLUS TABLETS with you so the doctor will know what you have taken.

## **4. Possible side effects**

ARTHROSAN PLUS TABLETS can have side effects.

Not all side effects reported for ARTHROSAN PLUS TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ARTHROSAN PLUS TABLETS, please consult your healthcare provider for advice.

If any of the following happens, stop taking ARTHROSAN PLUS TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, 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 allergic reaction to ARTHROSAN PLUS 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:

- chest pain;
- angina;
- changes in the way your heart beats, for example, if you notice it beating faster;
- difficulty breathing.

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

Tell your doctor if you notice any of the following:

*Side effects occurring frequently:*

- gastric discomfort;
- headache;
- shiitake dermatitis (skin eruption that resembles whiplash marks and occurs after consumption of raw shiitake mushrooms).

*Side effects occurring with an unknown frequency:*

- nausea (feeling sick);
- diarrhoea (runny, loose stool);
- constipation;
- vomiting (being sick);
- gastrointestinal obstruction (blockage in the intestines/gut);
- indigestion;
- mouth ulcers;
- trouble swallowing;
- liver problems;
- kidney problems;
- blood clotting problems;
- eosinophilia (a higher than normal level of eosinophils/white blood cells);
- sleep problems;
- malaise (a general feeling of discomfort);
- fatigue;
- light-headedness;
- decreased concentration;
- conjunctivitis (redness and inflammation of the thin layer of tissue that covers the front of the eye);
- photosensitivity (a condition in which the skin becomes very sensitive to sunlight);
- eyelid edema (swelling of the eyelids);
- lower limb edema (swelling of the lower limbs/legs);
- muscle tenderness;
- tremor (an involuntary quivering movement);
- fever;
- alopecia (hair loss);
- skin reactions;
- flushing (face becomes red and hot).

Side effects occurring rarely:

- acute liver injury that mimics autoimmune hepatitis.

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 the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ARTHROSAN PLUS TABLETS.

### 5. How to store ARTHROSAN PLUS TABLETS

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the container.
- Store in the original packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

### 6. Contents of the pack and other information

#### What ARTHROSAN PLUS TABLETS contains

Each tablet contains:

The active substances are:

Glucosamine sulphate (shellfish).....	500 mg
Methylsulfonylmethane (MSM).....	200 mg
Chondroitin sulphate (bovine).....	100 mg
<i>Lentinus edodes</i> (shiitake mushroom powder) [fruiting body, powder].....	75 mg
L-Ascorbic acid (Vitamin C).....	50 mg
Manganese glycinate.....	10 mg
providing manganese (elemental).....	1 mg
providing glycine.....	2,7 mg
Selenium glycinate.....	5 mg
providing selenium (elemental).....	10 µg
providing glycine.....	19 µg

The other ingredients are magnesium stearate (E572), Pharmaspec SX (base), Pharmaspec SX Peach coating, polyvinylpyrrolidone (PVP) K30.

Contains sweetener: Each tablet contains 290 mg sorbitol (E420).

Contains sugar alcohol: Each tablet contains 140 mg mannitol (E421).

#### What ARTHROSAN PLUS TABLETS looks like and contents of the pack

90 peach coloured oval tablets packed in a 400ml amber PET bottle with a gold PET screw cap.

#### Holder of Certificate of Registration

Brunel Laboratoria (Pty) Ltd  
1 Van Tonder Street  
Sunderland Ridge  
Centurion  
0157  
[info@brunel.co.za](mailto:info@brunel.co.za)

#### This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

**Registration number**

Will be allocated by SAHPRA upon registration.

**Access to the corresponding Professional Information**

The Professional Information for ARTHROSAN PLUS TABLETS is available on <https://www.brunel.co.za/professional-information/> or can be requested from the contact details above.

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## PASIËNTINLIGTINGSBLAD VIR ARTHROSAN PLUS TABLETTE

### SKEDULERINGSSTATUS

**S0**

#### ARTHROSAN PLUS TABLETTE

Glukosamiensulfaat (skulpvis), metielsulfonielmetaan (MSM), chondroïtiensulfaat (bees), *lentinus edodes* (shiitake sampioen poeier), L-askorbiensuur (vitamien C), mangaanglisinaat, seleniumglisinaat.

Bevat versoeter: Elke tablet bevat 290 mg sorbitol (E420).

Bevat suiker alkohol: Elke tablet bevat 140 mg mannitol (E421).

#### KOMPLEMENTÊRE MEDISYNE: KOMBINASIEPRODUK

**Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.**

**Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.**

ARTHROSAN PLUS TABLETTE is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy ARTHROSAN PLUS TABLETTE versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

#### Wat is in hierdie inligtingsblad

1. Wat ARTHROSAN PLUS TABLETTE is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy ARTHROSAN PLUS TABLETTE neem.
3. Hoe om ARTHROSAN PLUS TABLETTE te neem.
4. Moontlike newe-effekte.
5. Hoe om ARTHROSAN PLUS TABLETTE te bêre.
6. Inhoud van die verpakking en ander inligting.

#### 1. Wat ARTHROSAN PLUS TABLETTE is, en waarvoor dit gebruik word

ARTHROSAN PLUS TABLETTE bevat veelvuldige bestanddele om die gesondheid van jou bene en gewigte te verbeter en te onderhou.

#### 2. Wat jy moet weet voordat jy ARTHROSAN PLUS TABLETTE neem

**Moet nie ARTHROSAN PLUS TABLETTE neem:**

- indien jy onder die ouderdom van 18 jaar is nie;
- indien jy hipersensitief (allergies) is vir glukosamiensulfaat (skulpvis), metielsulfonielmetaan (MSM), chondroïtiensulfaat (bees), *lentinus edodes* (shiitake sampioen poeier), L-askorbiensuur (vitamien C), mangaanglisinaat, seleniumglisinaat of vir enige van die ander bestanddele van ARTHROSAN PLUS TABLETTE nie (sien **Wat ARTHROSAN PLUS TABLETTE bevat**);
- indien jy medikasie neem om bloedklonte te voorkom (antikoagulante).

#### Waarskuwings en voorsorgmaatreëls

Neem spesiale voorsorg met ARTHROSAN PLUS TABLETTE:

- indien jy probleme met jou lewer het;
- indien jy asma het;
- indien jy prostaatkanker het, of indien die kondisie in jou familie voorkom;
- indien jy gloukoom het (verhoogde druk in die oë);
- indien jy nierprobleme of niersiekte het;
- indien jy 'n diabeet is en medikasie neem om jou bloedsuikervlakke te beheer;
- indien jy hartprobleme of hartsiekte het;
- indien jy 'n geskiedenis het van nie-melanoom velkanker;
- indien jy enige chirurgiese prosedure ondergaan. Jy moet ARTHROSAN PLUS TABLETTE twee weke voor 'n operasie ophou neem.

## **Ander medisyne en ARTHROSAN PLUS TABLETTE**

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Vertel vir jou dokter of apteker indien jy tans die volgende gebruik:

- antikoagulant medikasie (gebruik om bloedklonte te voorkom), of enige natuurlike aanvullings wat bloedverdundingseffekte het.

## **ARTHROSAN PLUS TABLETTE met eet- en drinkgoed**

Sien afdeling 3 (**Hoe om ARTHROSAN PLUS TABLETTE te neem**).

## **Swangerskap, borsvoeding en vrugbaarheid**

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy die medisyne neem. Die veiligheid en effektiwiteit van ARTHROSAN PLUS TABLETTE tydens swangerskap en borsvoeding is nie vasgestel nie. Moet nie hierdie medisyne gebruik as jy swanger is of jou baba borsvoed nie.

## **Bestuur en die gebruik van masjiene**

Veiligheid en doeltreffendheid wanneer jy bestuur of masjiene gebruik, is nie vasgestel nie. Moet nie 'n voertuig bestuur, masjiene gebruik of enigiets anders doen wat jou aandag verg totdat jy weet hoe ARTHROSAN PLUS TABLETTE jou affekteer nie.

## **ARTHROSAN PLUS TABLETTE bevat mannitol (E421):**

ARTHROSAN PLUS TABLETTE bevat mannitol en kan 'n matige lakserende effek veroorsaak.

## **ARTHROSAN PLUS TABLETTE bevat sorbitol (E420):**

ARTHROSAN PLUS TABLETTE bevat sorbitol wat 'n bron is van fruktose. Indien jou dokter jou ingelig het dat jy onverdraagsaam vir sommige suikers is, kontak jou dokter voordat jy ARTHROSAN PLUS TABLETTE gebruik.

Sorbitol kan gastrointestinale ongemak en 'n matige lakserende effek veroorsaak.

## **3. Hoe om ARTHROSAN PLUS TABLETTE te neem**

Moet nie jou medisyne met enige ander persoon deel nie.

Neem ARTHROSAN PLUS TABLETTE altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus jou dokter of apteker indien jy onseker is.

Die gewone dosis is:

*Volwassenes (18 jaar en ouer):* Neem 3 tablette per dag na maaltye.

Indien jy die indruk kry dat die uitwerking van ARTHROSAN PLUS TABLETTE te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.

ARTHROSAN PLUS TABLETTE is slegs vir orale gebruik en moet met genoegsame vloeistof afgesluk word.

ARTHROSAN PLUS TABLETTE moet nie voor slaapyd geneem word nie.

ARTHROSAN PLUS TABLETTE moet nie deur kinders onder die ouderdom van 18 jaar geneem word nie.

## **As jy meer ARTHROSAN PLUS TABLETTE neem as wat jy moet**

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die houer met die oorblywende ARTHROSAN PLUS TABLETTE saam met jou sodat die dokter kan sien wat jy geneem het.

## **4. Moontlike newe-effekte**

ARTHROSAN PLUS TABLETTE kan newe-effekte hê.

Nie alle newe-effekte wat vir ARTHROSAN PLUS TABLETTE gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy ARTHROSAN PLUS TABLETTE neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om ARTHROSAN PLUS TABLETTE te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op ARTHROSAN PLUS TABLETTE gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Vertel jou dokter onmiddellik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy een van die volgende opmerk:

- borspyn;
- angina;
- veranderinge in die manier waarop jou hart klop, byvoorbeeld as jy sien dat dit vinniger klop;
- asemhalingsprobleme.

Hierdie is ernstige newe-effekte. Jy kan dringend mediese hulp benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

*Newe-effekte wat gereeld voorkom:*

- gastrointestinale ongemak;
- hoofpyn;
- shiitake dermatitis (veluitslag wat sweepsag merke voorstel en voorkom na die inname van rou shiitake sampioene).

*Newe-effekte wat voorkom met 'n onbekende frekwensie:*

- naarheid;
- diarree (los, loperige stoelgang);
- hardlywigheid;
- braking;
- gastrointestinale obstruksie (blokkasie in die ingewande/derm);
- onverteerbaarheid;
- mondsere;
- sukkel om te sluk;
- lewer-probleme;
- nier-probleme;
- bloedstollingsprobleme;
- eosinofilie ('n hoër as normale vlak van eosinofiele/witbloedselle);
- slaapprobleme;
- malaise ('n algemene gevoel van ongemak);
- moegheid;
- lighoofdigheid;
- verminderde konsentrasie;
- konjunktivitis (rooiheid en inflammasie van die dun vlies wat die oog bedek);
- fotosensitiwiteit ('n kondisie waar die vel baie sensitief is vir sonlig);
- ooglid edeem (swelling van die ooglede);
- onderste ledemaat edeem (swelling van die onderste ledemate/bene);
- spierteerheid;
- bewing ('n onwillekeurige bibberbeweging);
- koors;
- alopesie (haarverlies);
- velreaksies;
- blosing (gesig raak rooi en warm).

*Newe-effekte wat voorkom met 'n skaars frekwensie:*

- akute lewerbesering wat outo-immuun hepatitis naboots.



Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

### Aanmelding van nuwe-effekte

Indien jy nuwe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van ARTHROSAN PLUS TABLETTE te verskaf.

### 5. Hoe om ARTHROSAN PLUS TABLETTE te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C in 'n koel, droë plek, en beskerm teen lig.
- Moet nie in die badkamer bêre nie.
- Moet nie gebruik word na die vervaldatum wat op die houër gedruk is nie.
- Bêre in die oorspronklike verpakking.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

### 6. Inhoud van die verpakking en ander inligting

#### Wat ARTHROSAN PLUS TABLETTE bevat

Elke tablet bevat:

Die aktiewe bestanddele is:

Glukosamiensulfaat (skulpvis) .....	500 mg
Metielsulfoniemetaan (MSM) .....	200 mg
Chondroïtiensulfaat (bees) .....	100 mg
<i>Lentinus edodes</i> (shiitake sampioen poeier) [vrug, poeier] .....	75 mg
L-Askorbiensuur (Vitamiën C) .....	50 mg
Mangaanglisinaat .....	10 mg
lewer mangaan (elementaal) .....	1 mg
lewer glisien .....	2,7 mg
Seleniumglisinaat .....	5 mg
lewer selenium (elementaal) .....	10 µg
lewer glisien .....	19 µg

Die ander bestanddele is magnesiumstearaat (E572), Pharmaspec SX (basis), Pharmaspec SX Peach bedekking, polivinielpirrolidoon (PVP) K30 (E1201).

Bevat versoeter: Elke tablet bevat 290 mg sorbitol (E420).

Bevat suiker alkohol: Elke tablet bevat 140 mg mannitol (E421).

#### Hoe ARTHROSAN PLUS TABLETTE lyk en die inhoud van die verpakking

90 perske kleurige ovaal tablette verpak in 'n 400 ml amber PET houër met 'n goue PET skroefprop.

#### Houër van die Registrasiesertifikaat

Brunel Laboratoria (Edms) Bpk

Van Tonderstraat 1

Sunderland Ridge

Centurion

0157

[info@brunel.co.za](mailto:info@brunel.co.za)

#### Hierdie inligtingsblad is hersien in

Sal met registrasie deur SAHPRA aangedui word.

#### Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.

**Toegang tot die ooreenstemmende Professionele Inligtingsblad**

Die Professionele Inligtingsblad vir ARTHROSAN PLUS TABLETTE is beskikbaar by

<https://www.brunel.co.za/professional-information/> of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.

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