DONA®

PACKAGE INSERT

PROPRIETARY NAME AND DOSAGE FORM
DONA® 750 tablets
DONA® 1500 powder for oral solution

COMPOSITION
DONA® 750: Each film-coated tablet contains 942 mg Crystalline Glucosamine Sulfate, equivalent to 750 mg Glucosamine Sulfate and 192 mg Sodium Chloride.

DONA® 1500: Each sachet contains 1 884 mg Crystalline Glucosamine Sulfate, equivalent to 1 500 mg Glucosamine Sulfate and 384 mg Sodium Chloride

PHARMACOLOGICAL ACTION
The active ingredient glucosamine sulfate is the salt of an amino-monosaccharide glucosamine which is naturally present in the human body and promotes the incorporation of sulphur into the cartilage. Glucosamine penetrates the joint cartilage where it is involved in the synthesis of hyaluronic acid of the synovial fluid and the stimulation of glycosaminoglycans. It reduces pain, tenderness and swelling in the joints. The benefit of glucosamine sulfate in joint disease sufferers is the result of a number of effects including anti-inflammatory activity, stimulation of the synthesis of proteoglycans, and decrease in catabolic activity of chondrocytes. It inhibits the synthesis of proteolytic enzymes and other substances that contribute to damage cartilage matrix and the degradation of articular chondrocytes. Glucosamine is reported to reduce tenderness and swelling; alleviate painful joints; and improve mobility.

INDICATIONS
DONA® aids in the treatment of the symptoms of osteoarthritis:
- **DONA®** aids cartilage regeneration and maintains healthy cartilage.
- **DONA®** alleviates pain by reducing inflammation, swelling and stiffness.
- **DONA®** mobilizes the joints and improves mobility and movement.

CONTRA-INDICATIONS
Hypersensitivity to glucosamine or to any of the excipients.
The powder for oral solution contains aspartame and is therefore contra-indicated in patients with phenylketonuria.
Pregnancy - see **PREGNANCY AND LACTATION**

WARNINGS
Since glucosamine is obtained from shellfish, patients who are allergic to shellfish should exercise caution in the use of the product.
See also **SIDE EFFECTS AND SPECIAL PRECAUTIONS.**

INTERACTIONS
An increased effect of coumarinic anticoagulants during concomitant treatment with glucosamine sulfate may occur. Therefore, a closer monitoring of coagulation parameters may be required in these patients. Concurrent treatment with glucosamine sulfate may increase the gastro-intestinal absorption of tetracyclines.

Steroidal or non-steroidal analgesic or anti-inflammatory agents can be administered together with glucosamine sulfate.

PREGNANCY AND LACTATION
Contra-indicated in pregnancy.
Safety of use during lactation has not been established.
Women that have fertility problems should avoid using this product

DOSAGE AND DIRECTIONS FOR USE
Adults
DONA® 750 tablets:
Two tablets daily, preferably with a meal.
DONA® 1500 powder for oral solution:
The contents of one sachet (dissolved in a glass of water) once daily, preferably with a meal.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
The more commonly observed undesirable effects after oral administration are stomach pain, flatulence, constipation and diarrhoea.

Clinical trials have shown good tolerability of glucosamine sulfate. Side effects have been observed in a low proportion of patients. They were generally transient, not serious and can be subdivided according to the following frequency:

Organ System Class	Common ≥1/100 to ≤1/10	Uncommon ≥1/1000 to ≤1/100	Unkown*
Immune system disorders			Allergic reaction
Nervous system disorders	Headache Somnolence		
Eye disorders			Visual disturbances
Gastro-intestinal disorders	Diarrhoea Constipation Nausea Flatulence Stomach pain Dyspepsia		
Skin and subcutaneous tissue disorders		Erythema Pruritus Rash	Hair loss

*frequency cannot be estimated by the available data

DONA® 750 tablets contains 75.5 mg sodium per tablet. **DONA® 1500** powder for oral solution contains 151 mg sodium per sachet. The daily sodium intake is 151 mg. This must be taken into consideration by patients on a controlled sodium diet.
Administration to patients with severe hepatic or renal insufficiency should be under strict medical supervision.
Caution is advised in treatment of patients with impaired glucose tolerance. Closer monitoring of blood sugar levels may be necessary in diabetics at the beginning of treatment.

Safety and efficacy has not been established in children and in patients less than 18 years old, therefore administration in these patients should be avoided.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
No cases of accidental or intentional overdose are known. If overdose does occur treatment should be symptomatic e.g. act to restore hydro electrolytic balance.

IDENTIFICATION
DONA® 750 tablets: Oblong, white film-coated tablets, without break line.
DONA® 1500 powder for oral solution: White crystalline, odourless powder for oral solution.

PRESENTATION
DONA® 750 tablets: 60 film-coated tablets in a PE container, packed in a cardboard carton.
DONA® 1500 powder for oral solution: 30 sachets in a cardboard carton, each sachet containing 3,95 g powder.

STORAGE INSTRUCTIONS
Store at or below 25 °C in a cool, dry place protected from light.
KEEP OUT OF THE REACH OF CHILDREN

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

XIXIA PHARMACEUTICALS (PTY) LTD
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DATE OF PUBLICATION OF THE PACKAGE INSERT
20 June 2008

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www.mylansa.co.za

DONA®

VOUBILJET

EIENDOMSNAAM EN DOSEERVORM
DONA® 750 tablette
DONA® 1500 poeier vir orale oplossing

SAMESTELLING
DONA® 750: Elke film-bedekte tablet bevat 942 mg kristalvormige Glukosamiensulfaat, ekwivalent aan 750 mg Glukosamiensulfaat en 192 mg Natriumchloried.
DONA® 1500: Elke sakkie bevat 1 884 mg kristalvormige Glukosamiensulfaat, ekwivalent aan 1 500 mg Glukosamiensulfaat en 384 mg Natriumchloried.

FARMAKOLOGIESE AKSIE
Die aktiewe bestanddeel glukosamiensulfaat is die sout van 'n amino-monosakkaried glukosamien wat natuurlik in die menslike liggaam voorkom en die insluiting van sulfaat in kraakbeen bevorder. Glukosamien dring die gewrigskraakbeen binne, waar dit betrokke is by die sintese van hialuronsuur vir gewrigsvog en die stimulering van glukosamienglikane. Dit verminder pyn, inflammasie en swelling van die gewrigte. Die voordeel van glukosamiensulfaat vir lyers van gewrigssiektes is as gevolg van 'n aantal aktiwiteite, insluitend anti-inflammatoriese aktiwiteit, stimulering van proteoglikaansintese en vermindering van die kataboliese aktiwiteit van die chondrosiete. Dit inhibeer die sintese van proteïenoplossende ensieme en ander stowwe wat bydra tot die beskadiging van kraakbeen en die afbreking van gewrigs chondrosiete. Verslae bevestig dat Glukosamien teerheid en swelling verminder; seer gewrigte verlig; en beweeglikheid verbeter.

INDIKASIES
DONA® help in die behandeling van die simptome van osteoartritis:
- **DONA®** help in kraakbeen regenerasie en onderhou gesonde kraakbeen.
- **DONA®** verlig pyn deur inflammasie, swelling en styfheid te verminder.
- **DONA®** verminder gewrig styfheid en verbeter beweeglikheid en bewegings.

KONTRA-INDIKASIES
Hipersensitiwiteit vir glukosamien of van die ander bestandele
Die poeier vir orale oplossing bevat aspartaam en pasiënte met fenielketonurie behoort nie die produk te gebruik nie.
Swangerskap – sien **SWANGERSKAP EN LAKTASIE**

WAARSKUWINGS
Pasiënte wat allergies vir skulpvis is moet glukosamienbevattende produkte met versigtigheid gebruik.
Sien ook **NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS**

INTERAKSIES
Kumarien-antikoagulante se effek kan met gelyktydige behandeling van glukosamiensulfaat verhoog. Dit mag nodig wees om hierdie pasiënte se stollingsparameters strenger te monitor.

Gelyktydige behandeling met glukosamiensulfaat kan die gastro-intestinale absorpsie van tetrasikliene verhoog.

Steroïedale of nie-steroïedale analgetikums of anti-inflammatoriese middels kan saam met glukosamiensulfaat toegedien word.

SWANGERSKAP EN LAKTASIE
Swangerskap is 'n kontra-indikasie.
Die veilige gebruik van die middel tydens borsvoeding is nie vasgestel nie.
Vrouens wat 'n problem met vrugbaarheid het moet eerder nie die produk gebruik nie.

DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes
DONA® 750 tablette:
Twee tablette daagliks, verkieslik met 'n maaltyd.
DONA® 1500 poeier vir orale oplossing:
Die inhoud van een sakkie (opgelos in 'n glas water) een maal per dag verkieslik met 'n maaltyd.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS
Die mees algemeen ongewenste effek na mondelikse toediening is maagpyn, winderigheid, hardlywigheid en diaree.

Kliniese studies toon dat glukosamiensulfaat goed verdra word. Newe-effekte is by 'n klein persentasie van die pasiënte waargeneem. Dis is gewoonlik verbygaande, nie ernstig nie en die frekwensie daarvan kan soos volg onderverdeel word:

Klaas volgens Orgaansisteem	**Algemeen ≥1/100 to ≤1/10**	**Buitengewoon ≥1/1000 to ≤1/100**	**Onbekend***
Immuunsisteem afwykings			Allergiese reaksies
Senuweestelsel afwykings	Hoofpyn Slaperigheid		
Oog afwykings			Versteurde visie
Gastroïntestinale afwykings	Diaree Hardlywigheid Naarheid Winderigheid Maagpyn Dispepsie		
Vel en subkutane weefsel afwykings		Velrooiheid Jeuk Veluitslag	Haarverlies

*frekwensie kon nie met huidige data vasgestel word nie

DONA® 750 tablette bevat 75,5 mg natrium per tablet. **DONA® 1500** poeier vir orale oplossing bevat 151 mg natrium per sakkie. Daaglikse inname van natrium is 151 mg. Indien pasiënte op 'n gekontroleerde natrium dieet is, moet dit in ag geneem word. Toediening aan pasiënte met ernstige lewer of nierontoereikendheid behoort onder streng mediese toesig gedoen te geskied.

Wees versigtig indien pasiënte met ingekorte glukosetoleransie met glukosamien-bevattende produkte behandel word. By diabete mag noukeurige monitering van bloedsuikervlakke by die aanvang van behandeling nodig wees.

Veiligheid en effektiwiteit is nie by kinders en pasiënte onder die ouderdom van 18 vasgestel nie, daarom moet toediening by dié pasiënte vermy word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Geen gevalle van per ongeluk of opsetlike oordosering is bekend nie. In geval van 'n oordosis moet behandeling simptomaties wees, byvoorbeeld om die hidroëlektrolitiese balans te herstel.

IDENTIFIKASIE
DONA® 750 tablette: Langwerpig, wit film-bedekte tablette, sonder 'n keep.
DONA® 1500 poeier vir orale oplossing: Wit helder, reuklose poeier vir orale oplossing

AANBIEDING
DONA® 750 tablette: 60 film-bedekte tablette in 'n PE-houer, verpak in 'n kartonhouer.
DONA® 1500 poeier vir orale oplossing: 30 sakkies in 'n kartonhouer, elke sakkie bevat 3,95 g poeier.

BERGINGSAANWYSINGS
Bewaar teen of bende 25 °C in 'n koel, droë plek. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS

NAAM EN BESIGHEIDS ADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

XIXIA PHARMACEUTICALS (EDMS) LTD
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
20 Junie 2008

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