Health Canada Santé Canada

Product Licence
Licence de mise en marché

Product Number/*Numéro de produit*: 80078651
Brand Name/*Marque nominative*: VENIXXA
Issued to/*Émise à:*
Name of licensee/*Nom du titulaire:*

Servier Canada Inc.
235 boulevard Armand-Frappier
Laval, Quebec, H74 4A7
Canada

Authorized for the following/*Autorisé pour ce qui suit:*

Dosage form/*Forme posologique*: Tablet, film coated
Recommended route of administration/Voie *d'administration recommandée:*

Oral

Recommended dose/*Dose recommandée:*

Adults with Chronic venous disease (CVD) :	Take 1 tablet twice daily midday and evening with meals or as directed by health care practitioner.
Adults with Acute hemorrhoidal episode :	Swallow 3 tablets twice daily for the first 4 days, then 2 tablets twice daily for 3 days.
Adults with Hemorrhoids :	Swallow 1 tablets twice daily.

Recommended duration of use/*Durée d'utilisation recommandée:*

Chronic Venous Disease: Use for a minimum of 2 months to see beneficial effects. If response is inadequate or unsatisfactory after 2 months, consult a health care practitioner as edema may have alternative causes.
For use beyond 2 months, consult a health care practitioner.

Recommended use or purpose/*Usage ou les fins recommandés:*

Helps to reduce lower leg edema associated with mild-to moderate chronic venous disease.
Helps to relieve signs and symptoms of mild-to-moderate chronic venous disease such as varicose and spider veins, pain in the legs, sensation of heaviness, sensation of swelling and functional discomfort.
Helps to reduce signs and symptoms associated with hemorrhoids, such as anal discharge, bleeding, discomfort, inflammation (proctitis), itching (pruritus), pain, redness (erythema), sensation of needing to pass stools (tenesmus) and swelling (edema).
Helps to reduce the duration, intensity and recurrence of acute hemorrhoidal episodes.

Risk Information/*Renseignements sur les risques:*

Known Adverse Reactions

Hypersensitivity/allergy, gastrointestinal discomfort, dizziness, headaches, malaise and skin reactions have been known to occur; in which case, discontinue use and consult a health care practitioner.

Cautions and Warnings

Treatment should be avoided during pregnancy and breastfeeding. If symptoms of chronic venous disease persist or worsen consult a health care practitioner.
If you suffer, or experience inflammation of the skin, thrombophlebitis or subcutenious induration, severe pain, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency or disorder, consult a health care practitioner.
If symptoms persist or worsen, or if acute hemorrhoidal episode persists after 7 days, consult a health care practitioner.
If you are taking prescription medication, consult a healthcare practitioner prior to use.
If hemorrhoids are accompanied by rectal bleeding (bloody stools sometimes look like black tar), or if you experience change in bowel habit, consult a healthcare practitioner.

Medicinal Ingredients/*Ingrédients médicinaux:*

Proper Name Nom propre	Common Name Nom usuel	Quantity per Dosage Unit *Quantité par unité posologique*	Extract *Extrait*	Potency *Activité*	Source Material *Matière d'origine*
Citrus bioflavonoids	Citrus bioflavonoids	500 milligrams	N/A	90.0 % Diosmin	Citrus bioflavonoids (Synthetic)

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		N/A	N/A	10.0 % Flavonoids expressed as hesperidin	

This licence is issued by the Minister of Health under the authority of section 7 of the Natural Health Products Regulations. Sale of the described natural health product, including any changes thereto pursuant to section 11 of the Regulations, is subject to the Food and Drugs Act and to the Natural Health Products Regulations.
Cette licence est émise par la ministre de la Santé en vertu de l'article 7 du Règlement sur les produits de santé naturels. La vente du produit de santé naturel décrit dans la présente, y compris toute modification afférente au sens de l'article 11 du Règlement, est assujettie à la Loi sur les aliments et drogues et au Règlement sur les produits de santé naturels.

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Director General/ *Int. Directeur général*
NHPD/*DPSN*