

PROFESSIONAL INFORMATION

GUMMY VITES ELDERBERRY®	
SCHEDULING STATUS:	
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PROPRIETARY NAME AND DOSAGE FORM:	
Gummy Vites Elderberry Jelly Bear gums	
COMPOSITION:	
Each gum of 2,5 g contains:	
Sambucus nigra (30% polyphenols)	12,5 mg
Contains Sugar: Sucrose	1,20 g
Glucose	0,58 g
Sucrose syrup	0,26 g
List of Excipients: Citric acid, citrus pectin, glucose, raspberry flavours, rosehip extract, sucrose, trisodium citrate	
CATEGORY AND CLASS:	
Category D Complementary Medicine	
Discipline 33.6 Discipline-Specific. Western Herbals.	
PHARMACOLOGICAL ACTION:	
Pharmacodynamic Properties:	
<p>The applicable part of elderberry is the ripe fruit. Elderberries contain several flavonoids. The primary flavonoids are the anthocyanidins, including cyanidin 3-glucoside, cyanidin-3-sambubioside, and pelargonidin glucosides. Elderberries also contain quercetin, rutin, isoquercetin, and hyperoside, phytosterols, carotenoids, iron, copper, zinc, vitamins such as vitamin C, and minerals, such as magnesium. Elderberry also contains 3% tannins and essential oils, as well as fatty acids. The major protein of elderberry is a lectin called <i>Sambucus nigra</i> agglutinin IVf.</p>	
Antioxidant effects: The polyphenols in elderberry may be responsible for its antioxidant effects.	

<p>Immunological effects: The elderberry anthocyanidins are thought to have immunomodulating effects and possibly anti-inflammatory effects. Elderberry extract has both antiviral and immunomodulating effects. Elderberry extract also inhibits hemagglutinin activity and replication of several strains of influenza viruses A and B. <i>In vitro</i>, elderberry fruit extract also inhibits H1N1 "swine" flu. Elderberry flavonoids are thought to bind to H1N1 virions and prevent the virus from entering host cells. Elderberry also seems to increase production of inflammatory cytokines, such as interleukins and tumour necrosis factor.</p>
<p>Pharmacokinetic Properties:</p>
<p>Absorption:</p>
<p>The anthocyanidins in elderberry are detected in the plasma 30 minutes after ingestion. Peak concentrations appear to occur between 3-4 hours</p>
<p>Metabolism:</p>
<p>Elderberry leaves, stem, bark, seeds, and unripened fruit contain cyanogenic glycosides, which release cyanide when consumed. Glucuronidation of cyanidin from elderberry juice appears to be negligible.</p>
<p>Excretion:</p>
<p>The anthocyanidins in elderberry are excreted in the urine as glucuronide and sambubioside conjugates. The half-life of elderberry anthocyanidins is estimated to be about 2 hours, although some clinical evidence suggests that the half-life is 6 hours.</p>
<p>INDICATIONS:</p>
<p>Used in Herbal Medicine to promote sweating (diaphoretic), to help relieve fever (in cases of common colds, flus).</p>
<p>Used in Herbal Medicine to help relieve symptoms of colds and flus (such as coughs, sore throat and catarrh of the upper respiratory tract).</p>
<p>CONTRAINDICATIONS:</p>
<p>Gummy Vites Elderberry Jelly Bears are contraindicated in individuals allergic or sensitive to any of the listed ingredients. No other contraindications are known.</p>
<p>WARNINGS and SPECIAL PRECAUTIONS:</p>
<p>Do not use this product if you are hypersensitive (allergic) to any of the ingredients. Children on medication and pregnant or breastfeeding women must consult a doctor before use.</p>
<p>Do not exceed recommended dosages unless on the advice of a healthcare practitioner.</p>

Gummy Vites Elderberry Jelly Bears contains sucrose and glucose which may have an effect on the glycaemic control of patients with diabetes mellitus.
If symptoms persist or worsen, consult a health care practitioner.
INTERACTIONS:
Be watchful when taking Elderberry with Cytochrome P450 3 A4 (CYP3A4) substrates. Be cautious with the combination of Elderberry & Immunosuppressants. Elderberry seems to stimulate production of cytokines including interleukin and tumor necrosis factor. Theoretically, elderberry might exacerbate autoimmune disease by stimulating disease activity. Advise patients with autoimmune diseases such as multiple sclerosis, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others to avoid taking elderberry.
HUMAN REPRODUCTION:
Safety for use during pregnancy and lactation has not been established. Pregnant or breastfeeding women must consult a doctor before use.
DOSAGE AND DIRECTIONS FOR USE:
Recommended daily dosage:
Age 1 to 3 years: 1 to 2 jelly bears twice daily
Age 4 years and over: 2 to 3 jelly bears twice daily
Maximum dosage: 8 Jelly bears per day
Recommended for children over 12 months. Also suitable for adults.
SIDE EFFECTS:
Side effects may include nausea, vomiting, diarrhoea and colic.
Diuretic effect may occur.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Treatment should be symptomatic and supportive. In the case of accidental overdose of the product, contact the nearest hospital or poison control centre.
IDENTIFICATION:

Raspberry-flavoured bear-shaped gums
PRESENTATION:
Gummy Vites Elderberry Jelly Bears gums are packed in white HDPE bottles of 30's and 120's
STORAGE INSTRUCTIONS:
Store in a cool dry place at or below 25 °C.
KEEP OUT OF REACH OF CHILDREN.
KEEP THE CONTAINER TIGHTLY CLOSED
REGISTRATION NUMBER:
TBA
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Adcock Ingram Limited 1 New Road Midrand, 1635 South Africa www.adcock.com
DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
TBA
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.