

OVAPRIM- sgnrha and domperidone injection, solution
Western Chemical Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Ovaprim® Injectable Solution

(Salmon Gonadotropin Releasing Hormone Analog 20 µg/ml + Domperidone 10 mg/ml) For intraperitoneal or intramuscular injection in ornamental finfish broodstock only.

Not for use in fish intended for human or animal consumption.

Not for use in fish whose offspring may be consumed by humans or food-producing animals.

NOT APPROVED BY FDA – Legally marketed as an FDA Indexed Product under MIF 900-001.

Extra-label use is prohibited.

Note---In order to be legally marketed, an animal drug product intended for a minor species must be Approved, Conditionally Approved, or Indexed by the FDA. **THIS PRODUCT IS INDEXED.**

It is a violation of federal law to use this product in a manner other than as directed in the labeling. As used on this label, the words “ornamental fish” refer to a wide variety of finfish species maintained primarily for their appearance and do not include any fish that are consumed by humans or food-producing animals.

NET CONTENTS: 10 ml

DESCRIPTION:

Ovaprim® is a liquid peptide preparation that contains an analog of salmon gonadotropin releasing hormone (sGnRH_a) and a brain neurotransmitter (dopamine) inhibitor. The sGnRH_a in Ovaprim® elicits the release of stored gonadotropins from the pituitary. The dopamine inhibitor (Domperidone) serves to remove other inhibition of GnRH release. Release of stored pituitary gonadotropins may aid spawning by stimulating ovulation and spermiation in sexually mature fish.

INDICATION: For intraperitoneal or intramuscular use as a spawning aid in ornamental finfish broodstock.

CAUTION:

FOR USE IN ORNAMENTAL FINFISH BROODSTOCK ONLY; THIS PRODUCT IS NOT TO BE USED IN ANIMALS INTENDED FOR USE AS FOOD FOR HUMANS OR OTHER ANIMALS.

WARNING:

Care should be taken to avoid accidental contact or self-injection. In the event of accidental self-injection, seek medical advice immediately. Use in a well ventilated area. Wear gloves, goggles and suitable protective clothing. Not for use in humans. Keep out of the reach of children.

INHALATION: May be harmful. If breathing becomes difficult, move to fresh air, and contact a physician.

INGESTION: May be harmful. If the person is conscious, wash out mouth with copious amounts of

water. Contact a physician.

EYE CONTACT: May be harmful. In case of contact, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Contact a physician.

SKIN CONTACT: May be harmful. In case of contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and wash before re-using. Contact a physician.

OTHER HEALTH INFORMATION: The toxicological properties of sGnRHa have not been thoroughly investigated. The actions are similar to luteinizing hormone releasing hormone (LHRH, Gonadotropin releasing hormone, GnRH) in humans. LHRH is the key mediator in the liberation of the pituitary gonadotropins, luteinizing hormone (LH) and follicle stimulating hormone (FSH). LHRH may modify reproductive ability by influencing plasma gonadotropin levels and concomitantly gonadal steroid levels.

To obtain a product Safety Data Sheet, call Syndel USA at (360) 384-5898.

DIRECTIONS FOR USE:

Ovaprim® is packaged ready for use in liquid form. Precise amounts for individual injections should be withdrawn directly from the bottle into a syringe. Due to the viscosity of the product, use of syringes with Luer Lock tips or permanently attached needles is strongly recommended. Use of syringes with slip tips is not recommended since needles could inadvertently eject under pressure.

CLEANLINESS: Syringes/needles should be sterile prior to use.

LOADING: Withdraw only enough solution from the bottle of Ovaprim® Injectable Solution as will be required for the weight of the fish. With the needle pointed upward and directed away from your face, squeeze the syringe gently to expel any trapped air.

INJECTION: Hold the fish firmly and insert the needle into the abdominal cavity/belly between the pelvic fin and the vent or into the muscle on either side of the dorsal fin. For intra-abdominal injection in smaller species, it may be helpful to secure the fish on a soft wet surface such as a sponge, and to place the fish on its side and inject into the rear abdominal cavity to avoid contact with internal organs. Inject Ovaprim® carefully. After injection, gently place the fish into a container of clean aerated water.

SEDATION FOR HANDLING AND RECOVERY: If necessary, sedate broodstock prior to Ovaprim® injection.

DOSE:

A general dose of Ovaprim® is 0.5 ml per kilogram of bodyweight. This dose may vary among finfish species and physiological state of individual animals. Environment and temperature also play a significant role in the reproductive process and may affect dose and timing. For most species, only a single dose of Ovaprim® is required; but treatment of fish with a single dose of Ovaprim® is only effective in fish that are within or near their natural spawning season. For other species, a split dose may be needed. For split dosing, a loading dose of 10% of the total dose should be injected, followed by injection of the remaining 90% of the total dose at least 6 hours later. In warm water species, ovulation may occur in as little as 4 hours post treatment, so fish should be monitored accordingly. Signs of ovulation/spermiation may include a noticeable swelling and “softening” of the abdomen; presence of eggs in the water; the ability to easily express eggs from the female and milt from males; and when sexes are held together in the same tank, onset of spawning behavior (e.g., males “chasing” females). However, it is important to note that the interval between treatment and the onset of ovulation is variable between species and temperature, and treated fish should be disturbed as little as possible to reduce stress during final maturation. Males may respond in shorter periods of time than females of the same species.

DOSE CALCULATION:

The dose is calculated based on the weight of the fish.

	FISH WEIGHT	x	OVAPRIM® DOSAGE	=	AMOUNT OF INJECTION
Examples:	1) 0.2 kg		0.5 ml/kg		0.1 ml
	2) 50 gm		0.5 µl/gm		25 µl

Use of a needle guard to limit the penetration of the needle into the fish may be helpful, and use of a tuberculin or similar syringe is also recommended for accurate dosing in small fish and to minimize trauma at the injection site. Intramuscular injection may result in bleeding at the injection site. Swelling, ulceration, whiteness, redness, or hypopigmentation may also be observed at the injection site.

STORAGE AND HANDLING:

Store below 25°C and protect from sunlight and sources of heat.

DISPOSAL:

Contact your State Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance pertaining to disposal of unused product.

QUESTIONS/COMMENTS? For technical assistance, call Syndel USA at (360) 384-5898. To report an adverse event, call Syndel USA at (360) 384-5898, or FDA at 1-888-FDA-VETS.

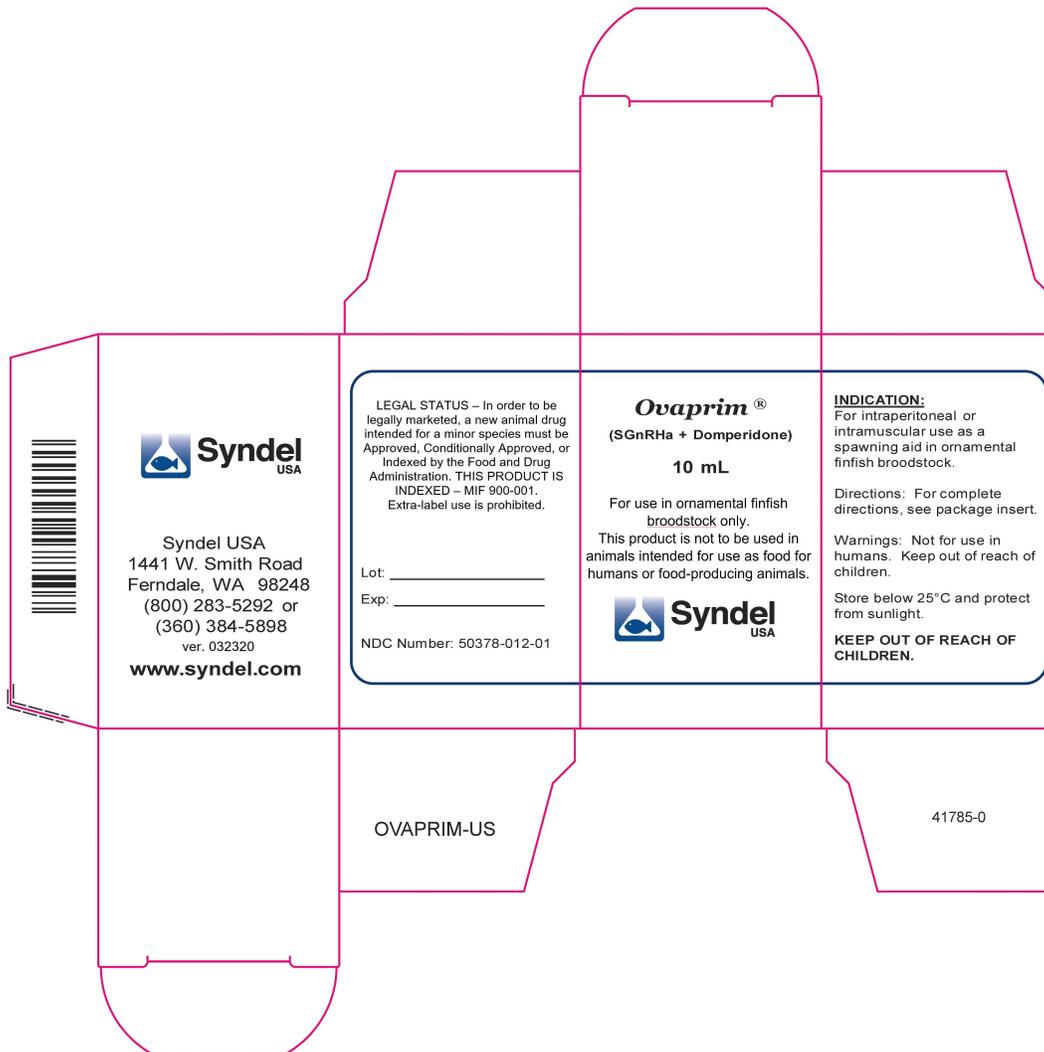
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NDC Number: 50378-012-01

Syndel USA Ovaprim Indexed Box v. 032320.jpg

Syndel USA Ovaprim Indexed Label Sheet v. 032320.jpg



OVAPRIM

sgnrha and domperidone injection, solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:50378-012
Route of Administration	INTRAPERITONEAL, INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALMON GONADOTROPIN RELEASING HORMONE D-ARG6 ANALOG ETHYL	SALMON GONADOTROPIN	20 ug

AMIDE ACETATE (UNII: 66KW0E903I) (SALMON GONADOTROPIN RELEASING HORMONE D-ARG6 ANALOG ETHYL AMIDE - UNII:WHI058 YG4Q)	RELEASING HORMONE D-ARG6 ANALOG ETHYL AMIDE	20 ug in 1 mL
Domperidone (UNII: 5587267Z69) (Domperidone - UNII:5587267Z69)	Domperidone	10 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50378-012-01	10 mL in 1 VIAL, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Legally Marketed Unapproved New Animal Drugs for Minor Species	MIF900001	02/11/2009	

Labeler - Western Chemical Inc. (085803500)

Registrant - Western Chemical Inc. (085803500)

Establishment

Name	Address	ID/FEI	Business Operations
Western Chemical Inc.		085803500	label, analysis

Revised: 8/2020

Western Chemical Inc.