

CHORULON- gonadotrophin, chorionic
Merck Sharp & Dohme Corp.

CHORULON®

Approved by FDA under NADA # 140-927

FOR ANIMAL USE ONLY

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

CHORULON® is a freeze-dried preparation of chorionic gonadotropin (human Chorionic Gonadotropin or hCG) for intramuscular administration after reconstitution. When reconstituted with the accompanying sterile diluent, each 10 mL vial contains 10,000 I.U. chorionic gonadotropin (equivalent to 10,000 USP Units chorionic gonadotropin) and 10 mg mannitol, with mono- and disodium phosphate to adjust the pH of the solution.

ACTION

Chorionic gonadotropin has luteinizing hormone-like activity with little or no follicle stimulating or estrogenic activity.

INDICATIONS

COWS: CHORULON® is indicated for intramuscular use in cows for the treatment of nymphomania (frequent or constant heat) due to cystic ovaries.

FINFISH: CHORULON® is indicated for use as an aid in improving spawning function in male and female brood finfish.

DOSAGE AND ADMINISTRATION

To reconstitute, transfer the contents of one vial of sterile diluent into one vial of freeze-dried powder. The resulting 10 mL of CHORULON® contains 10,000 I.U. chorionic gonadotropin.

COWS: The contents of one vial (10 mL) of reconstituted CHORULON® should be administered as a single deep intramuscular injection. Dosage may be repeated in 14 days if the animal's behavior or rectal examination of the ovaries indicates the necessity for retreatment.

FINFISH: CHORULON® should be administered via intramuscular injection just ventral to the dorsal fin for one (1) to three (3) injections. Any single injection should be administered, depending on the fish species, at a dose of 50 to 510 I.U./lb body weight (bw) for males and 67 to 1816 I.U./lb bw for females. Depending on body weight and dose administered, it may be necessary to divide the dose among two or more injection sites to avoid injecting a large volume at a single site.

Summaries of doses tested in representative fish species are contained within the following tables. The dose of CHORULON® to be used in other species of finfish may differ from those species listed in the tables, but should fall within the suggested range of 50 to 510 I.U./lb bw for males and 67 to 1816 I.U./lb bw for females.

Table 1: Tested Fish Species/Dose Combinations Found to be Effective

Nomenclature Common Name, <i>Genus & Species, Family</i>	Tested Dose(s) (I.U./lb bw/injection)		Number of Injections Injection Interval (h)
	Males	Females	
yellow perch, <i>Perca flavescens</i> , Percidae	nt ¹	67-300	1 -
striped bass, <i>Morone saxatilis</i> , Percichthyidae	50-500	75-252	1 -
white bass, <i>Morone chrysops</i> , Percichthyidae	65-510	91-750	1 -
razorback sucker, <i>Xyrauchen texanus</i> , Catostomidae	nt	100	3 24
walleye, <i>Stizostedion vitreum</i> , Percidae	75-400	145-830	1-3 72
red snapper, <i>Lutjanus campechanus</i> , Lutjanidae	250	500	1 -
sauger, <i>Stizostedion canadense</i> , Percidae	500	500-1000	1 -
Chinese catfish, <i>Clarius fuscus</i> , Clariidae	nt	1816	1 -

Footnotes: 1, nt = not tested

Table 2: Tested Fish Species/Dose Combinations Found to be Safe

Nomenclature Common Name, <i>Genus & Species, Family</i>	Tested Dose(s) (I.U./lb bw/injection)		Number of Injections Injection Interval (h)
	Males	Females	
white bass, <i>Morone chrysops</i> , Percichthyidae	750	1500	1 -
walleye, <i>Stizostedion vitreum</i> , Percidae	750	1500	1 -
grass carp, <i>Ctenopharyngodon idella</i> , Cyprinidae	2500	5000	1 -
channel catfish, <i>Ictalurus punctatus</i> , Ictaluridae	2500	5000	1 -

ADVERSE REACTIONS

Chorionic gonadotropin is a protein. in the unlikely event of an anaphylactic reaction, epinephrine should be administered. the administration of an antihistamine may also be indicated.

RESIDUE WARNINGS

No withdrawal period is required for cows or brood finfish treated according to label directions. the total dose administered (all injections combined) should not exceed 25,000 i.u. (25 mL) per fish in fish intended for human consumption.

STORAGE AND HANDLING PRECAUTIONS

Store at or below room temperature, 77° F (25°C). Keep out of reach of children. once reconstituted, CHORULON® should be used immediately. unused solution should be disposed of properly and not stored for future use.

HOW SUPPLIED

CHORULON® is supplied in cartons containing five vials of freeze-dried powder and five 10 mL vials of sterile diluent. order Code No. CH-475-1.

Intervet Inc., d/b/a Merck Animal Health
Rahway, NJ 07065

Manufactured by:
Intervet International GmbH
Unterschleissheim, Germany

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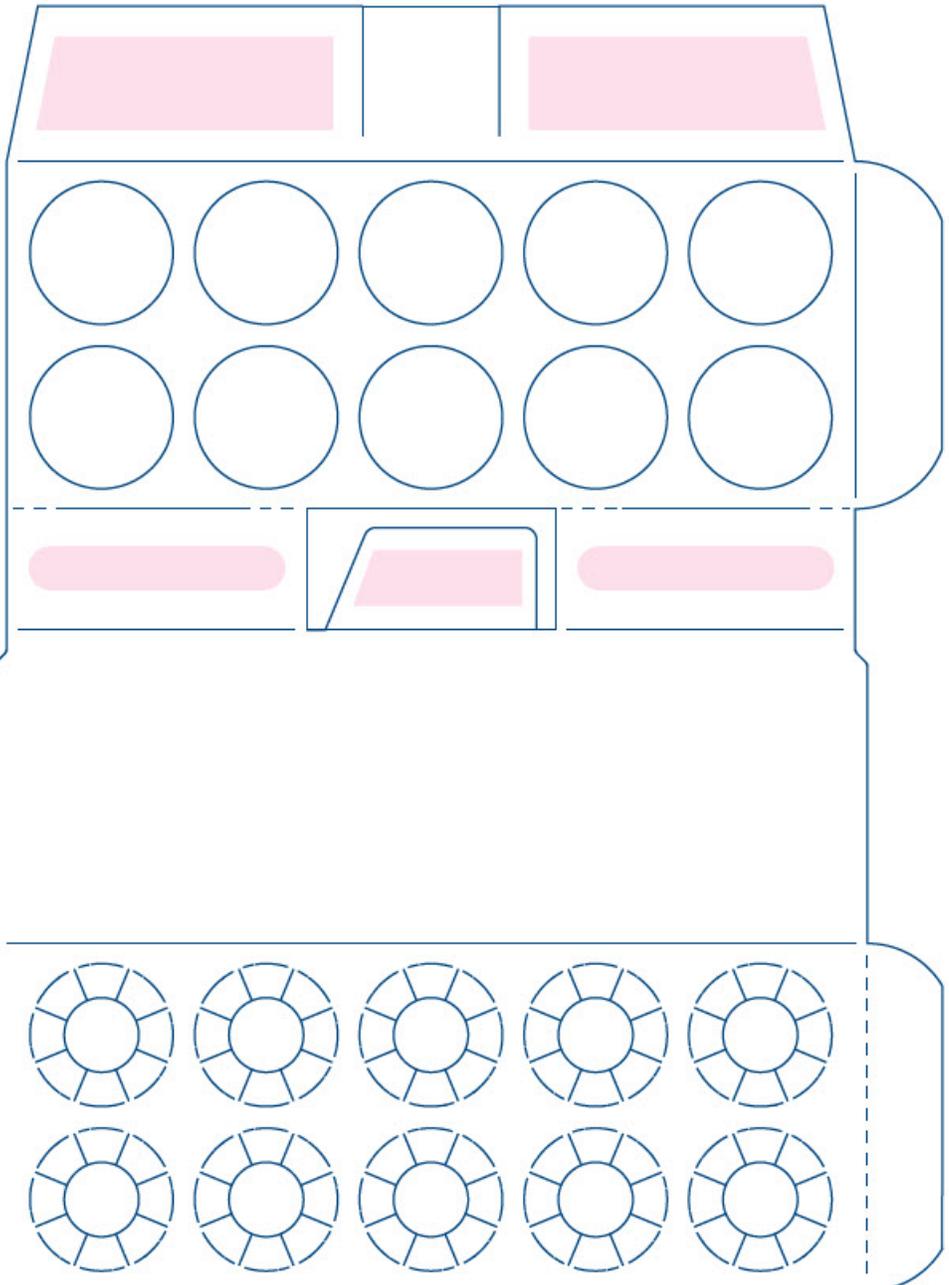
395398 R2

PRINCIPAL DISPLAY PANEL - Kit Carton

5 vials with diluent

chorulon®
(chorionic gonadotropin)

MERCK
Animal Health



Manufactured for:
Intervet Inc., d/b/a Merck Animal Health
Rahway, NJ 07065
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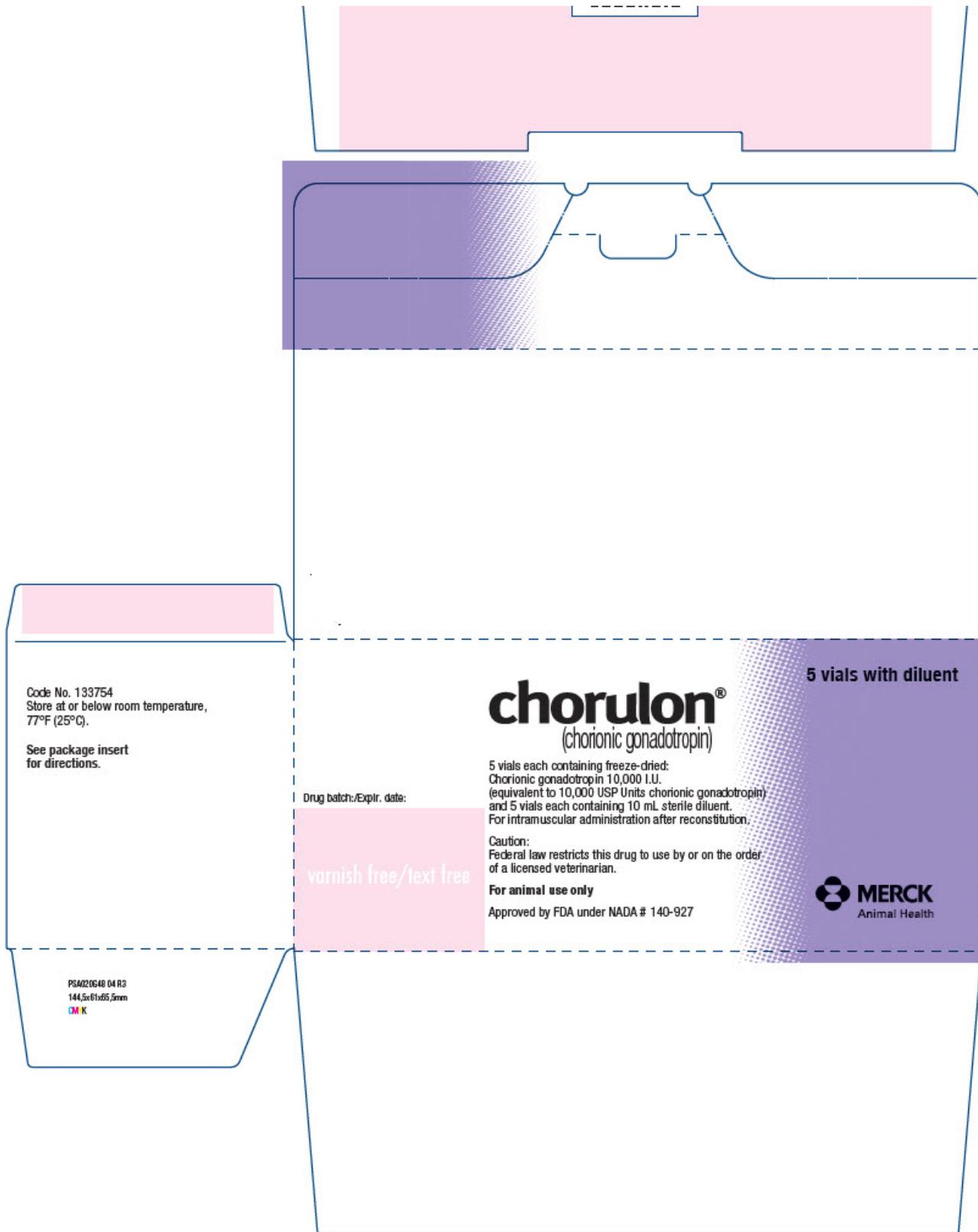
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307106 R2

chorulon[®]
(chorionic gonadotropin)

5 vials with diluent





CHORULON

gonadotrophin, chorionic kit

Product Information

Product Type

PRESCRIPTION ANIMAL DRUG

Item Code (Source)

NDC:57926-475

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57926-475-62	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	5 VIAL	5
Part 2	5 VIAL	50 mL

Part 1 of 2

CHORULON

gonadotrophin, chorionic injection, powder, lyophilized, for solution

Product Information

Route of Administration INTRAMUSCULAR

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHORIONIC GONADOTROPIN (UNII: 20ED16GHEB) (CHORIONIC GONADOTROPIN - UNII:20ED16GHEB)	CHORIONIC GONADOTROPIN	10000 [iU]

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140927	11/22/1991	

Part 2 of 2

DILUENT FOR CHORULON

sterile phosphate buffered water injection, solution

Product Information

Route of Administration INTRAMUSCULAR

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140927	11/22/1991	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140927	11/22/1991	

Labeler - Merck Sharp & Dohme Corp. (001317601)

Establishment

Name	Address	ID/FEI	Business Operations
Intervet International GMBH		328855635	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Renjian Pharmaceutical Group Co., Ltd.		529358491	API MANUFACTURE

Revised: 11/2023

Merck Sharp & Dohme Corp.