



SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 15 mg, 30 ct Bottle	NDC 64950-560-03
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 15 mg, 100 ct Bottle	NDC 64950-560-01
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 15 mg, 1000 ct Bottle	NDC 64950-560-10
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 16.2 mg, 30 ct Bottle	NDC 64950-541-03
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 16.2 mg, 100 ct Bottle	NDC 64950-541-01
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 16.2 mg, 1000 ct Bottle	NDC 64950-541-10
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 30 mg, 30 ct Bottle	NDC 64950-561-03
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 30 mg, 100 ct Bottle	NDC 64950-561-01
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 30 mg, 1000 ct Bottle	NDC 64950-561-10
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 32.4 mg, 30 ct Bottle	NDC 64950-542-03
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 32.4 mg, 100 ct Bottle	NDC 64950-542-01
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 32.4 mg, 1000 ct Bottle	NDC 64950-542-10
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 60 mg, 30 ct Bottle	NDC 64950-562-03
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 60 mg, 100 ct Bottle	NDC 64950-562-01
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 60 mg, 1000 ct Bottle	NDC 64950-562-10
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 64.8 mg, 30 ct Bottle	NDC 64950-543-03
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 64.8 mg, 100 ct Bottle	NDC 64950-543-01
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 64.8 mg, 1000 ct Bottle	NDC 64950-543-10
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 97.2 mg, 30 ct Bottle	NDC 64950-544-03
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 97.2 mg, 100 ct Bottle	NDC 64950-544-01
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 97.2 mg, 1000 ct Bottle	NDC 64950-544-10
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 100 mg, 30 ct Bottle	NDC 64950-563-03
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 100 mg, 100 ct Bottle	NDC 64950-563-01
Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary, 100 mg, 1000 ct Bottle	NDC 64950-563-10

Product Name: Fidoquel™ (Phenobarbital CIV) Tablets, Veterinary

Recommended use: Veterinary Fidoquel™ (Phenobarbital CIV) Tablets are indicated in dogs 6 months of age and older, for the control of seizures associated with idiopathic epilepsy in dogs. It can be used as a lone therapy or along with other drugs to decrease the frequency and severity of the pet's seizures. This medication is also used for a short time (usually no more than 2 weeks) to help the pet to be calm and/or to sleep during periods of anxiety.



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Restrictions:

Veterinary FidoquelTM (Phenobarbital CIV) Tablets should not be used in dogs with a history of hypersensitivity to Phenobarbital. Not for use in humans or cats. Do not use FidoquelTM in pregnant or lactating dogs since it may produce congenital malformations in the developing fetus. Phenobarbital may be present and accumulate in the milk of lactating dogs. Phenobarbital CIV may interact with other drugs so consult with a veterinarian if the pet is on other medication.

Manufacturer Name:
Manufacturer Address:

Genus Lifesciences Inc.
514 N. 12th Street
Allentown, PA 18102

Telephone number:
Fax number:

(610) 782-9780 ext.*100
(610) 782-9781

Medical Information Line:

1-833-599-7582

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

The product FidoquelTM (Phenobarbital CIV) Veterinary Tablets is a non-hazardous pharmaceutical mixture and does not meet OSHA's Hazard Communication Standard (HCS) 2012, 29CFR 1910.1200 and OSHA's Globally Harmonized System (GHS) hazard criteria. As per OSHA section 1910.1200(b)(6)(vii), "Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient; drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment" are exempt. The GHS hazards listed below are for the active product ingredient (API), Phenobarbital CIV, and not for the Tablet finished product itself.

Physical hazards:

Not classified

Health hazards:

Acute Toxicity Oral Category 3
Skin Sensitization Category 1
Carcinogenicity Category 2
Reproduction Toxicity (Fertility and unborn child) Category 1B
Specific Target Organ Toxicity, Single Exposure Category 3 Narcotic Effects

Environmental hazards:

Not classified

Signal Word:

Warning

Hazard Statement:

This product is a DEA Schedule IV controlled substance. Substances in the DEA Schedule IV have a low potential for abuse and low risk of dependence. Phenobarbital is a barbiturate and a central nervous system (CNS) depressant with a potential for misuse, abuse, and addiction.



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Pictogram:



Precautionary Statement:

Because Phenobarbital may cause developmental effects, women who are pregnant or may become pregnant should handle and administer Fidoquel™ with caution. Barbiturates can be extremely dangerous because overdoses can occur easily and lead to death. Read label before use.

Hazards Not Otherwise Classified: None known.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*

Chemical Identity	Other Names	CAS Number
Colloidal Silicon Dioxide, NF	Cab-O-Sil, Quartz, Dioxosilane	7631-86-9
Lactose Monohydrate, NF	SuperTab 11SD	64044-51-5
Magnesium Stearate, NF	N/A	557-04-0
Microcrystalline Cellulose, NF	Avicel PH102	9004-34-6
Phenobarbital, USP (Active Ingredient)	N/A	50-06-6
Sodium Starch Glycolate, NF	Explotab	9063-38-1

* Chemical exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 – FIRST AID MEASURES

Eye Contact: Not an expected route of exposure under normal conditions for the finished product. If exposure happened, flush with water while holding eyelids open for at least 15 minutes. Remove contact lenses if worn. Seek medical attention if irritation or discomfort persists.

Skin Contact: Not an expected route of exposure under normal conditions for the finished product. If exposure happened, wash the skin with soap and large amount of water. Contact medical personnel if irritation persists.

Ingestion: This product is intended for ingestion. Do not use more than prescribed dose. Taking more medication will not improve the symptoms; rather they may cause poisoning or serious side-effects. If an overdose occurs, taken not as prescribed, or an accidental ingestion of large amounts occurs, call a physician or a Poison Control Center (1-800-222-1222) immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.



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Inhalation: Not an expected route of exposure under normal conditions for the finished product. If breathing is difficult, move to fresh air and seek medical attention immediately.

Symptoms or effects: Symptoms of intoxication with barbiturates include unsteady walk and sustained nystagmus. Mental signs of intoxication include confusion, poor judgment, irritability, and insomnia. Phenobarbital may produce physical dependence and narcotic effects. Abrupt discontinuation or rapid dosage reduction of Phenobarbital may precipitate acute withdrawal reactions, including seizures, which can be life-threatening. Tolerance may occur with continued use.

Recommendations: Immediate medical attention is required if an overdose is suspected. Call a Poison Control Center (1-800-222-1222) if needed. No action shall be taken involving any personal risk or without suitable training. Do **NOT** induce vomiting due to potential CNS depression.

Note to Physician: Phenobarbital is a barbiturate that sometimes humans use and abused to reduce anxiety, decrease inhibitions, and treat unwanted effects of illicit drugs. Consider the potential risks of misuse or abuse before prescribing this product to dogs or owners with history of use or abuse of illicit drugs. Provide general supportive measures and treat symptomatically. In severely poisoned patients, consider multiple doses of activated charcoal. Cathartics are **NOT** recommended. Urinary alkalization may enhance clearance of Phenobarbital.

Dogs with decreased liver function may be predisposed to phenobarbital toxicosis. Some dogs may experience epileptic episodes that are refractory or unresponsive to FidoquelTM monotherapy. Careful monitoring of therapeutic, biochemical, and hematology parameters is important in dogs receiving FidoquelTM. Dogs receiving FidoquelTM should also be carefully monitored when administering concurrent medications.

Dogs should be monitored for adverse events when adjusting the dose to determine the optimal dose for each patient. Monitor vital signs and fluid balance. Maintain adequate airway with assisted respiration and administration of oxygen. Maintain blood pressure and body temperature. For shock, administer fluid therapy or other standard treatment. **AVOID** fluid or sodium overload. Take appropriate care to prevent hypostatic pneumonia, aspiration, and other complications. For pneumonia, take appropriate cultures and administer antibiotics. The exposed person may need to be kept under medical surveillance for 48 hours.

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing media: Use Water, Dry chemical, CO₂ or any material appropriate for fire in the surrounding area. Do not use water jet as an extinguisher, as this might spread the fire.

Specific hazards arising from the mixture: None known, however gases hazardous to health might be formed (Refer to section 10)



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Advice to the firefighters:

Wear appropriate protective clothing and equipment, including self-contained breathing apparatus.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

- Personal Precautions:** No action shall be taken involving any personal risk or without suitable training. Clean the spill if it is safe to do so. Minimize exposure. Keep unnecessary personnel away. Do not touch or walk through spilled material.
- Protective Equipment:** Safety Glasses or goggles, gloves, protecting clothes. (Refer to section 8)
- Emergency procedures:** Evacuate the area. Keep unnecessary personnel away. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.
- Containment Precautions:** Isolate area around spill as specified by site procedures.
- Clean Up Procedures:** Use suitable absorbent material. Collect the material in a compatible container. Dispose according to applicable regulations (Refer to section 13). Decontaminate with water.

SECTION 7 – HANDLING AND STORAGE

- Precaution for safe handling:** Observe safe industrial practices. No special handling requirements for normal use of this material. Dispense content with a child resistant closure and in a tight, light-resistant container as defined in the USP/NF.
- Conditions for safe storage:** Store in original container, at a locked Controlled Room or in a locked cabinet according to federal and state controlled substance requirements and guidelines. Temperature at 25°C (77°F), excursions are permitted to 15° - 30°C (59° - 86°F). Protect from Moisture and Light. Keep container tightly closed and out of reach of children. For more information follow directions in product packaging.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

There are no exposure limits for the FidoquelTM (Phenobarbital CIV) Veterinary Tablets finished products. The exposure limits listed below are for the active product ingredient (API) Phenobarbital CIV and not for the Tablets finished product itself.



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OSHA Permissible Exposure Limits (PELs):	None
Occupational Exposure Limit (OEL's):	10 µg/m ³
Acceptable Daily Exposure (ADE):	30 µg/day
5 Band System Exposure Classification:	Category 3 – High
ACGIH Threshold Limit Values (TLVs):	
Short Term Exposure Limits (STEL) – 15 min:	Not Available
Time Weight Average (TWA) – 8 Hours:	Not Available
NIOSH Immediately Dangerous to Life or Health (IDLH):	None

Engineering Controls: Not required when handling tablets or containers. Ventilation should match conditions.

Personal Protective Measures:

Respiratory protection:	None required when handling tablets. If it found to be necessary, wear a mask or an appropriate NIOSH approved respirator.
Eye protection:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Protective gloves:	Not required under normal conditions of use. Chemical compatible when needed.
Skin and body protection:	Not required under normal conditions of use.
Hygiene measures:	Wash hands, forearms and face thoroughly after handling chemical products, before eating and at the end of working period. Contaminated work clothing should not be allowed out of the workplace. Wash clothing before reusing.
Other personal protection:	None required

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Appearance:	Bisected Tablets	Odor:	Odorless
Density:	Not Available	Boiling Point:	Not available
Melting Point:	Not Applicable	Solubility:	Water, Alcohol, and Ether



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Viscosity: Not Available Specific Gravity: Not Available

Evaporation Rate: Not Available Conductivity: Not Available

Chemical Properties:

pH: Not Available Flash Point: Not Available

Reactivity: Refer to section 10 Toxicity: Refer to section 11

SECTION 10 – STABILITY AND REACTIVITY

Reactivity: None expected under normal conditions of use.

Chemical stability: Stable under normal conditions of use.

Other:

Conditions to avoid:	Moisture and heat.
Incompatible materials:	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products:	None known

SECTION 11 – TOXICOLOGICAL INFORMATION

Routes of exposure: Ingestion

Delayed, immediate and chronic effects for short and long term exposure:

General effects:	Narcotic effects, dizziness, drowsiness, confusion, anxiety, weakness, uncontrolled eye movement, incoordination, insomnia, depression, gastrointestinal disturbances.
Sensitization:	Phenobarbital is a skin sensitizer. Allergic skin reaction may occur when exposed to some levels.
Mutagenic effects:	No known significant effects or critical hazards.
Reproductive toxicity:	Phenobarbital is suspected of damaging fertility. Therapeutic use during the last trimester of pregnancy may cause physical dependence and



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withdrawal in the newborn. Barbiturates are distributed into the milk of nursing women; nursing should be discontinued if using the product.

Fetotoxic / Teratogenic Effects: Phenobarbital is suspected of damaging the fetus. Some barbiturates have been shown to cause an increased incidence of fetal abnormalities.

Specific Target Organ Toxicity (STOT):

Single exposure:	Narcotic effects Category 3
Repeated exposure:	There is no data available.

Toxicity (LD₅₀):

Toxicity studies have not been conducted with the FidoquelTM (Phenobarbital CIV) Veterinary Tablets finished products. The exposure limits listed below are for the active product ingredient (API) Phenobarbital CIV and not for the Tablets finished product itself.

Oral LD ₅₀ Rat:	162 mg/kg	Subcutaneous (SC) LD ₅₀ Rat:	200 mg/kg
Intraperitoneal (IP) LD ₅₀ Rat:	110 mg/kg	Intravenous (IV) LD ₅₀ Rat:	209 mg/kg
Rectal LD ₅₀ Rat:	284 mg/kg	Oral LD ₅₀ Mouse:	137 mg/kg
Subcutaneous LD ₅₀ Mouse:	228 mg/kg	Intravenous (IV) LD ₅₀ Mouse:	218 mg/kg
Intramuscular LD ₅₀ Mouse:	175 mg/kg	Intraperitoneal LD ₅₀ Mouse:	88 mg/kg
Oral LD ₅₀ Rabbit:	185 mg/kg	Intravenous (IV) LD ₅₀ Rabbit:	187 mg/kg
Oral LD ₅₀ Dog:	150 mg/kg	Oral LD ₅₀ Guinea Pig:	130 mg/kg

Symptoms / Adverse Reactions:

Common general adverse reactions seen are ataxia, lethargy, increased water consumption, increased appetite, vomiting, increased urination, hyperactivity, diarrhea, and weight gain.

The hematologic adverse reactions include increased serum alkaline phosphatase (ALP), increased serum alanine transferase (ALT), increased serum gamma-glutamyl transferase (GGT), decreased serum total and free thyroxine (T4) concentrations, immune-mediated anemia, neutropenia, and thrombocytopenia. Rarely, idiosyncratic hepatotoxicity may also occur.

Nervous system: Agitation, somnolence, confusion, CNS depression, hyperkinesia, ataxia, nervousness, nightmares, psychiatric disturbance, thinking abnormality, insomnia, anxiety, hallucinations, dizziness.

Dermatologic: Exfoliative dermatitis and toxic epidermis necrolysis.



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Carcinogenicity:

Product not listed as a carcinogen by OSHA. API Phenobarbital is suspected of causing cancer. The risk of cancer depends on duration and level of exposure.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects):

Ecotoxicity studies have not been conducted with the FidoquelTM (Phenobarbital CIV) Veterinary Tablets finished products. The exposure limits listed below are for the active product ingredient (API) Phenobarbital CIV and not for the Tablets product itself.

LC₅₀ Daphnia magna (Water flea): 1,460 mg/L for 24 hrs.

LC₅₀ Pimephales promelas Fish (Fathead minnow): 484 mg/L for 96 hrs.

Persistence and Degradability:

If released to air, an estimated vapor pressure of 1.4X10⁻¹¹ mm Hg at 25 °C indicates that Phenobarbital will exist solely in the particulate phase in the atmosphere. Particulate phase Phenobarbital will be removed from the atmosphere by wet or dry deposition.

If released to soil is expected to have high mobility based upon an estimated Koc of 59. The pKa of Phenobarbital is 7.3, indicating that this compound will exist partially in the anion form in the environment and anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts.

If released into water, Phenobarbital is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Phenobarbital, present at 100 mg/L, reached 0% of its theoretical BOD in 4 weeks.

Bioaccumulation:

An estimated BCF of 4 suggests the potential for bioconcentration in aquatic organisms low. Phenobarbital is not expected to volatilize from dry soil surfaces.

Leaching studies:

Phenobarbital is expected to have high mobility in soil.

Other adverse effects:

The pharmaceutical product is not classified as environmentally hazardous. No major harmful effects to aquatic organisms are expected, however; is highly recommended to avoid environmental releases.



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SECTION 13 – DISPOSAL INFORMATION

Disposal Containers: Dispose used or contaminated containers in accordance with Drug Enforcement Administration (DEA) guidelines and the federal, state or local regulatory requirements.

Waste Disposal Methods: Dispose of waste in accordance with Drug Enforcement Administration (DEA) guidelines and the federal, state or local regulatory requirements. Any unused or expired bottles must be destroyed by a reverse distributor.

Special Precautions: Discard away from children's reach. Releases to the sewer should be avoided.

SECTION 14 – TRANSPORT INFORMATION

USDOT - Department of Transportation:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under USDOT.

ICAO - International Civil Aviation Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under ICAO.

IATA - International Air Transport Association:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IATA.

IMDG/IMO - International Maritime Dangerous Goods / International Maritime Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IMDG/IMO.

Special Precautions: None Known

SECTION 15 – REGULATORY INFORMATION

Drug Enforcement Administration (DEA): Listed as Schedule IV Controlled Substances (CIV).



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Food and Drug Administration (FDA):

Approved prescription medication.

Occupational Safety and Health Administration (OSHA):

GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

SARA 302/304 Extreme Hazardous Substances (EHS):

Not Listed

SARA 313 Toxic Chemical Release Inventory (TRI):

Not Regulated

SARA 311/312 Hazard Categories:

Immediate Hazard – Yes

Delayed Hazard – Yes

Fire Hazard – No

Pressure Hazard – No

Reactivity Hazard – No

Resource Conservation and Recovery Act (RCRA):

No Code Applicable

Clean Water Act (CWA):

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Clean Air Act (CAA):

This product does not contain any chemicals listed under Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

Environmental Response Compensation and Liability Act (CERCLA):

Not applicable for the product. This product, as supplied, do not contains substances regulated as hazardous substances under CERCLA (40 CFR 302). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

Toxic Substances Control Act (TSCA):

Not applicable for the product. The following ingredients are included on the TSCA inventory 8(b):



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Ingredient	CAS No
Colloidal Silicon Dioxide, NF	7631-86-9
Magnesium Stearate, NF	557-04-0
Microcrystalline Cellulose, NF	9004-34-6
Sodium Starch Glycolate, NF	9063-38-1

SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Creation Date: Apr/01/25, New SDS

Revision Date: N/A

This Safety Data Sheet cancels and replaces all preceding SDS for this product.

Genus Lifesciences Inc. believes that the information contained herein is based on the best available data at the date of preparation. However, no warranty is expressed or implied regarding the data's accuracy and completeness. Since the use of this information and the conditions of use of this material are not within the control of Genus Lifesciences Inc., it is the user's obligation to determine the conditions of safe use of this material.