HALOPERIDOL TABLET 0.5 mg, 1mg, 2mg, 5mg, 10mg and 20mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Haloperidol tablets are indicated for use in the management of manifestations of psychotic disorders. *See full prescribing information for complete details.*
2	Dosage	What is the recommended dosage?	Oral Administration Initial Dosage Range Adults Moderate Symptomatology - 0.5 mg to 2 mg b.i.d. or t.i.d. Severe Symptomatology - 3 mg to 5 mg b.i.d. or t.i.d. To achieve prompt control, higher doses may be required in some cases. Geriatric or Debilitated Patients - 0.5 mg to 2 mg b.i.d. or t.i.d. Chronic or Resistant Patients - 3 mg to 5 mg b.i.d. or t.i.d. *See full prescribing information for complete details.*
3	Administration	How do I take it?	Haloperidol Tablets should be administered Orally.
4	Administration	What do I do if I miss a dose?	Take Haloperidol Tablets exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking Haloperidol Tablets without first talking to your healthcare provider. *In case, if you miss a dose, please contact your treating physician.*
5	Administration	Use in Pediatric Population	Safety and effectiveness in pediatric patients have not been established.
6	Administration	Use in Geriatric Population	The pharmacokinetics of haloperidol in geriatric patients generally warrants the use of lower doses *See full prescribing information for complete details.*
7	Mechanism	Mechanism of Action	The precise mechanism of action has not been clearly established
8	Warning	Black Box Warning	Increased Mortality in Elderly Patients with Dementia-Related Psychosis *See full prescribing information for complete boxed warning.*
9	Pregnancy	Use in Pregnancy	This drug should be used during pregnancy or in women likely to become pregnant only if the benefit clearly justifies a potential risk to the fetus. Infants should not be nursed during drug treatment.

			See full Prescribing Information for complete information.
10	Precautions	Is there any interaction between medication and alcohol?	The use of alcohol with this drug should be avoided due to possible additive effects and hypotension.
11	Storage	What are the storage conditions?	Store at 20˚to 25˚C (68˚to 77˚F). Protect from light. Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.
12	Dispensing	How to Dispense?	Protect from light. Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.
13	Contraindication	What are the contraindications of (medication).	Haloperidol tablets are contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.
Pharmaceutical Particulars			
14	Pharmaceutical Form	How is it supplied?	Haloperidol 0.5 mg tablets available as follows: NDC 72205-064-91 bottles of 100 tablets, NDC 72205-064-99 bottles of 1000 tablets Haloperidol 1 mg tablets are available as follows: NDC 72205-065-91 bottles of 100 tablets, NDC 72205-065-99 bottles of 1000 tablets Haloperidol 2 mg tablets are available as follows: NDC 72205-066-91 bottles of 100 tablets, NDC 72205-066-99 bottles of 1000 tablets Haloperidol 5 mg tablets are available as follows: NDC 72205-067-91 bottles of 100 tablets, NDC 72205-067-99 bottles of 1000 tablets Haloperidol 10 mg tablets are available as follows: NDC 72205-068-91 bottles of 100 tablets Haloperidol 20 mg tablets are available as follows: NDC 72205-069-91 bottles of 100 tablets
15	Ingredients	Active and Inactive Ingredients	**Active ingredient:** HALOPERIDOL **Inactive ingredients:** colloidal silicon dioxide, D&C Yellow No. 10 Aluminum Lake, magnesium stearate, microcrystalline cellulose, pregelatinized starch and sodium lauryl sulfate. In addition, the 10 mg and 20 mg tablets also contain FD&C Blue No. 1 Aluminum Lake.
Miscellaneous			
16	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products
17	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500.

18	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company
19	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report SUSPECTED ADVERSE REACTIONS, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1- 800-FDA-1088 or www.fda.gov/medwatch.
20	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products.
21	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** MSN Pharmaceuticals Inc. Piscataway, NJ 08854 **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714 Issued on: February 2021