

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-176




APPROVED DRAFT LABELING

Haloperidol Decanoate

100 mg/mL Vial Carton #0931031

Colors: 514 Pink, Reflex Blue, 185 Red, 123 Yellow, Black & Varnish

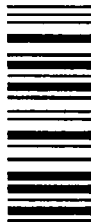
Size: 1.3125" x 1.3125" x 1.8125"

<p>NDC 60793-081-05 Haloperidol Decanoate Injection 100 mg/mL as haloperidol 5 mL Multiple Dose Vial Sterile IM Use Only</p>			
<p>NDC 60793-081-05 Haloperidol Decanoate Injection 100 mg/mL as haloperidol 5 mL Multiple Dose Vial Sterile IM Use Only Rx Only  Manufactured by King Pharmaceuticals, Inc. Bristol, TN 37620</p>	<p>NDC 60793-081-05 *Each mL contains 100 mg haloperidol as 141 mg haloperidol decanoate in a sesame oil vehicle, with 1.2% (w/v) benzyl alcohol as a preservative. For Intramuscular Use Only</p>	<p>NDC 60793-081-05 Haloperidol Decanoate Injection 100 mg/mL as haloperidol 5 mL Multiple Dose Vial Sterile IM Use Only Rx Only  Manufactured by King Pharmaceuticals, Inc. Bristol, TN 37620</p>	<p>Usual Dosage: For dosage and other prescribing information, see accompanying product literature. The dose of Haloperidol Decanoate Injection should be expressed in terms of its haloperidol content. Store at controlled room temperature (15°-30°C, 59°-86°F). Do not refrigerate or freeze. PROTECT FROM LIGHT. Retain in carton until contents are used. Rev. 8/99 0931031</p>
<p> 931031 unvarnished for lot and exp.</p>			

200%

unvarnished
for lot and exp.

931903



NDC 60793-081-05

**Haloperidol
Decanoate Injection**

100 mg/mL

Rx only

*as haloperidol
5 mL Multiple Dose Vial Sterile

IM Use Only

Mfg. by: King Pharmaceuticals, Inc.
Bristol, TN 37620

For Intramuscular Use Only
Usual Dosage: For dosage and other prescribing information, see accompanying product literature. The dose of Haloperidol Decanoate Injection should be expressed in terms of its haloperidol content. Store at controlled room temperature (15°-30° C, 59°-86°F). Do not refrigerate or freeze. Protect from light.

Rev. 8/99 0931903

unvarnished
for lot and exp.

931903



NDC 60793-081-05

**Haloperidol
Decanoate Injection**

100 mg/mL Rx only
*as haloperidol
5 mL Multiple Dose Vial Sterile

IM Use Only

Mfg. by: King Pharmaceuticals, Inc.
Bristol, TN 37620

For Intramuscular Use Only
Usual Dosage: For dosage and other prescribing information, see accompanying product literature. The dose of Haloperidol Decanoate Injection should be expressed in terms of its haloperidol content. Store at controlled room temperature (15°-30° C, 59°-86°F). Do not refrigerate or freeze. Protect from light.

Rev. 8/99 0931903

Haloperidol Decanoate
 100 mg/mL Vial Carton #0931030
 Colors: 514 Pink, Reflex Blue, 185 Red, 123 Yellow, Black & Varnish
 Size: L - 2.75" W -.625" D - 3.0625"

Decanoate Injection
 Haloperidol
 100* mg/mL
 NDC 60793-080-05 5 x 1-mL
 *as haloperidol

NDC 60793-080-05

Haloperidol Decanoate Injection

100* mg/mL

*as haloperidol
 5 x 1-mL AMPULES Sterile **IM Use Only**

Each mL contains 100 mg haloperidol as 141 mg haloperidol decanoate in a sesame oil vehicle, with 1.2% (w/v) benzyl alcohol as a preservative.

Store at controlled room temperature 15°-30°C (59°-86°F).
 Do not refrigerate or freeze.

Rx only.

For Intramuscular Use Only.



Manufactured by
 King Pharmaceuticals, Inc.
 Bristol, TN 37620

PROTECT FROM LIGHT
 Retain in carton until time of use.

Usual Dosage: For dosage and other prescribing information, see accompanying product literature.

The dose of Haloperidol Decanoate Injection should be expressed in terms of its haloperidol content.

Dispense in a light-resistant container as defined in the official compendium.

100* mg/mL
 *as haloperidol
 5 x 1-mL
IM Use Only
 Haloperidol Decanoate Injection

For your convenience
 in recording use

Initial Date

1	_____	_____
2	_____	_____
3	_____	_____
4	_____	_____
5	_____	_____

100* mg/mL
 *as haloperidol
 5 x 1-mL
IM Use Only
 Haloperidol Decanoate Injection



931030

unvarnished
 for lot and exp.

NDC 60793-080-01
1 mL IM Use Only
**Haloperidol
Decanoate Injection**
100* mg/mL
*as haloperidol
Mfg. by: King Pharmaceuticals, Inc.
Bristol, TN 37620
0931902 Rev. 8/99

200%




NDC 60793-080-01
1 mL IM Use Only
**Haloperidol
Decanoate Injection**
100* mg/mL
*as haloperidol
Mfg. by: King Pharmaceuticals, Inc.
Bristol, TN 37620
0931902 Rev. 8/99

Haloperidol Decanoate

50 mg/mL Vial Carton #0931033

Colors: 300 Blue, Reflex Blue, 185 Red, 123 Yellow, Black & Varnish

Size: 1.3125" x 1.3125" x 1.8125"

<p>IM Use Only *as haloperidol 5 mL Multiple Dose Vial Sterile</p> <p>50* mg/mL</p> <p>Haloperidol Decanoate Injection</p> <p>NDC 60793-083-05</p>			
<p>NDC 60793-083-05</p> <p>Haloperidol Decanoate Injection</p> <p>50* mg/mL</p> <p>*as haloperidol 5 mL Multiple Dose Vial Sterile</p> <p>IM Use Only</p> <p>Rx Only</p> <p> Manufactured by King Pharmaceuticals, Inc. Bristol, TN 37620</p>	<p>NDC 60793-083-05</p> <p>*Each mL contains 50 mg haloperidol as 70.5 mg haloperidol decanoate in a sesame oil vehicle, with 1.2% (w/v) benzyl alcohol as a preservative.</p> <p>For Intramuscular Use Only</p>	<p>NDC 60793-083-05</p> <p>Haloperidol Decanoate Injection</p> <p>50* mg/mL</p> <p>*as haloperidol 5 mL Multiple Dose Vial Sterile</p> <p>IM Use Only</p> <p>Rx Only</p> <p> Manufactured by King Pharmaceuticals, Inc. Bristol, TN 37620</p>	<p>Usual Dosage: For dosage and other prescribing information, see accompanying product literature.</p> <p>The dose of Haloperidol Decanoate Injection should be expressed in terms of its haloperidol content.</p> <p>Store at controlled room temperature (15°-30°C, 59°-86°F).</p> <p>Do not refrigerate or freeze. PROTECT FROM LIGHT.</p> <p>Retain in carton until contents are used.</p> <p>Rev. 8/99 0931033</p>
<p> 931033</p> <p>unvarnished for lot and exp.</p>			

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unvarnished
for lot and exp.

931907



NDC 60793-087-01

**Haloperidol
Decanoate Injection**

50* mg/mL Rx only

*as haloperidol
5 mL Multiple Dose Vial Sterile

IM Use Only

Mfg. by: King Pharmaceuticals, Inc.
Bristol, TN 37620

For Intramuscular Use Only
Usual Dosage: For dosage and other prescribing information, see accompanying product literature. The dose of Haloperidol Decanoate Injection should be expressed in terms of its haloperidol content. Store at controlled room temperature (15°-30° C, 59°-86°F). Do not refrigerate or freeze. Protect from light.

Rev. 8/99 0931907

unvarnished
for lot and exp.

931907



NDC 60793-087-01

**Haloperidol
Decanoate Injection**

50* mg/mL Rx only

*as haloperidol
5 mL Multiple Dose Vial Sterile

IM Use Only

Mfg. by: King Pharmaceuticals, Inc.
Bristol, TN 37620

For Intramuscular Use Only
Usual Dosage: For dosage and other prescribing information, see accompanying product literature. The dose of Haloperidol Decanoate Injection should be expressed in terms of its haloperidol content. Store at controlled room temperature (15°-30° C, 59°-86°F). Do not refrigerate or freeze. Protect from light.

Rev. 8/99 0931907

Haloperidol Decanoate
 50 mg/mL Vial Carton #0931032
 Colors: 300 Blue, Reflex Blue, 185 Red, 123 Yellow, Black & Varnish
 Size: L - 2.75" W - 1.25" D - 3.0625"

*as haloperidol
50* mg/mL
Haloperidol
Decanoate Injection

NDC 60793-082-01 10 x 1-mL


NDC 60793-082-01

Haloperidol
Decanoate Injection
50* mg/mL

*as haloperidol
 10 x 1-mL AMPULES Sterile **IM Use Only**

*Each mL contains 50 mg haloperidol as 70.5 mg haloperidol decanoate in a sesame oil vehicle, with 1.2% (w/v) benzyl alcohol as a preservative.
 Store at controlled room temperature 15°-30°C (59°-86°F). Do not refrigerate or freeze.
Rx only.
 For intramuscular Use Only.

PROTECT FROM LIGHT
 Retain in carton until time of use.
Usual Dosage: For dosage and other prescribing information, see accompanying product literature.
 The dose of Haloperidol Decanoate Injection should be expressed in terms of its haloperidol content.
 Dispense in a light-resistant container as defined in the official compendium.


 Manufactured by
 King Pharmaceuticals, Inc.
 Bristol, TN 37620

*as haloperidol
 10 x 1-mL
IM Use Only

50* mg/mL
Haloperidol
Decanoate Injection


For your convenience
 in recording use

	Initial	Date
1	_____	_____
2	_____	_____
3	_____	_____
4	_____	_____
5	_____	_____
6	_____	_____
7	_____	_____
8	_____	_____
9	_____	_____
10	_____	_____

 Manufactured by
 King Pharmaceuticals, Inc.
 Bristol, TN 37620

*as haloperidol
 10 x 1-mL
IM Use Only

50* mg/mL
Haloperidol
Decanoate Injection


 931032

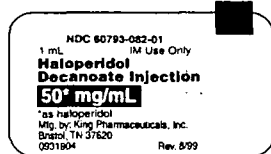
unvarnished
 for lot and exp.

Haloperidol Decanoate

50 mg/mL - 1 mL Ampule #0931904

Size: 13 /8" x 3/4"

Colors: 300 Blue, 185 Red, Black, Varnish



200%

