

**ROLFIA- crataegus oxy, passiflore inc, rauwolfia ser, kali brom tablet**  
**Adven Biotech Private Limited**

*Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.*

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**Rolfia Tablets**

Crataegus Oxyacantha, Passiflora Incarnata, Rauwolfia Serpentina, Kali Bromatum

**Adults:** Take 2 tablets with water every 8 hours.

**Children under 18 years:** Please consult physician.

**Warnings:**

If symptoms persist or worsen, a physician should be consulted. **Keep out of reach of children. Do not use**, if known sensitivity to any of its ingredients exists. **Replace cap tightly. If pregnant or breast feeding**, ask a health care professional before use.

Tones up the Heart Muscle, Controls hypertension. Decrease Blood Pressure

**Uses:**

Normalizes high blood pressure, controls hypertension, tones up the heart muscle, treats arteriosclerosis and related symptoms like sleeplessness, irritability.

Sugar of milk

Do not use if neck wrap or foil inner seal is broken or missing. Protect from moisture, direct sunlight and heat.

	Side A	Side B																																							
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**ROLFIA**

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**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69825-007
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM BROMIDE (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06)	POTASSIUM BROMIDE	3 [hp_X] in 100 g
CRATAEGUS MONOGYNA LEAF (UNII: A2KER9748T) (CRATAEGUS MONOGYNA LEAF - UNII:A2KER9748T)	CRATAEGUS MONOGYNA LEAF	2 [hp_X] in 100 g
PASSIFLORA INCARNATA ROOT (UNII: 3952I8DXEX) (PASSIFLORA INCARNATA ROOT - UNII:3952I8DXEX)	PASSIFLORA INCARNATA ROOT	2 [hp_X] in 100 g
RAUWOLFIA SERPENTINA (UNII: H192N84N1G) (RAUWOLFIA SERPENTINA - UNII:H192N84N1G)	RAUWOLFIA SERPENTINA	2 [hp_X] in 100 g

## Inactive Ingredients



Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	

## Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69825-007-02	1 in 1 BOX	03/30/2016	
1	NDC:69825-007-01	100 g in 1 BOTTLE; Type 0: Not a Combination Product		

 <p>Net Wt. 100 gm 400 Tablets, 250 mg each</p>	<p>Side A</p> <table border="1"> <thead> <tr> <th>Drug Facts</th> </tr> </thead> <tbody> <tr> <td> <b>Active Ingredients Purpose</b>                      Crataegus Oxy.....Tones up the Heart Muscle                      Passiflora Inc.....Controls Hypertension                      Rauwolfia Ser.....Decreases Blood Pressure                      Kali Brom.....Controls Hypertension                 </td> </tr> <tr> <td> <b>Uses :</b> Normalizes high blood pressure, controls hypertension, tones up the heart muscle, treats arteriosclerosis and related symptoms like sleeplessness, irritability.                 </td> </tr> <tr> <td> <b>Warnings:</b>                      If symptoms persist or worsen, a physician should be consulted. <b>Keep out of reach of children. Do not use, if known sensitivity to any of its ingredients exists. Replace cap tightly. If pregnant or breast feeding, ask a health care professional before use.</b> </td> </tr> <tr> <td> <b>Directions :</b>  <b>Adults:</b> Take 2 tablets with water every 8 hours.  <b>Children:</b> Please consult physician.                 </td> </tr> <tr> <td> <b>Other Information :</b>                      Do not use if neck wrap or foil inner seal is broken or missing. Protect from moisture, direct sunlight and heat.                 </td> </tr> </tbody> </table>	Drug Facts	<b>Active Ingredients Purpose</b> Crataegus Oxy.....Tones up the Heart Muscle Passiflora Inc.....Controls Hypertension Rauwolfia Ser.....Decreases Blood Pressure Kali Brom.....Controls Hypertension	<b>Uses :</b> Normalizes high blood pressure, controls hypertension, tones up the heart muscle, treats arteriosclerosis and related symptoms like sleeplessness, irritability.	<b>Warnings:</b> If symptoms persist or worsen, a physician should be consulted. <b>Keep out of reach of children. Do not use, if known sensitivity to any of its ingredients exists. Replace cap tightly. If pregnant or breast feeding, ask a health care professional before use.</b>	<b>Directions :</b> <b>Adults:</b> Take 2 tablets with water every 8 hours. <b>Children:</b> Please consult physician.	<b>Other Information :</b> Do not use if neck wrap or foil inner seal is broken or missing. Protect from moisture, direct sunlight and heat.	<p>Side B</p> <table border="1"> <thead> <tr> <th>Drug Facts (Continued)</th> </tr> </thead> <tbody> <tr> <td> <b>Inactive Ingredients</b>                      Sugar of milk                 </td> </tr> <tr> <td> <b>Questions?</b>                      Email : wecare@adven.in                 </td> </tr> <tr> <td> <b>The statements on this package are supported by traditional homeopathic principles. The Food and Drug Administration does not evaluate homeopathic products.</b> </td> </tr> <tr> <td> <b>Composition :</b> Crataegus Oxy 2x HPI 10% w/w, Passiflora Inc 2x HPI 10% w/w, Rauwolfia Ser 2x 10% w/w, Kali Brom 3x HPI 10% w/w, Sugar of milk q.s to 250 mg.                 </td> </tr> <tr> <td> <b>Mfg. Date :</b>  <b>Expiry Date :</b>  <b>Batch Number :</b> </td> </tr> <tr> <td> <b>Manufactured for and Distributed by:</b>                      PAAHM LLC                      Chatsworth, CA 91311, USA                 </td> </tr> <tr> <td> <p style="text-align: center;">Product of India For Export Only</p> </td> </tr> </tbody> </table>	Drug Facts (Continued)	<b>Inactive Ingredients</b> Sugar of milk	<b>Questions?</b> Email : wecare@adven.in	<b>The statements on this package are supported by traditional homeopathic principles. The Food and Drug Administration does not evaluate homeopathic products.</b>	<b>Composition :</b> Crataegus Oxy 2x HPI 10% w/w, Passiflora Inc 2x HPI 10% w/w, Rauwolfia Ser 2x 10% w/w, Kali Brom 3x HPI 10% w/w, Sugar of milk q.s to 250 mg.	<b>Mfg. Date :</b> <b>Expiry Date :</b> <b>Batch Number :</b>	<b>Manufactured for and Distributed by:</b> PAAHM LLC Chatsworth, CA 91311, USA	<p style="text-align: center;">Product of India For Export Only</p>
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		03/30/2016	

## Establishment

Name	Address	ID/FEI	Business Operations
Adven Biotech Private Limited		858029164	manufacture(69825-007) , re-label(69825-007) , re-pack(69825-007)

Revised: 4/2016

Adven Biotech Private Limited