SINA-12X
Suspension

IN-6302-01 Rev. 1/03

Description
SINA-12X is a nasal decongestant/expectorant available for oral administration as a suspension.
Each 5 mL (one teaspoonful) of the purple-colored, grape flavored suspension contains:

Phenylephrine Tannate	5 mg
Guaifenesin	100 mg

Other ingredients: benzoic acid, FD&C Blue No. 1, FD&C Red No. 3, FD&C Red No. 40, flavors (natural and artificial), glycerin, kaolin, magnesium aluminum silicate, methylparaben, pectin, purified water, saccharin sodium, sodium hydroxide, sucrose.

Clinical Pharmacology
Phenylephrine is a sympathomimetic nasal decongestant which acts predominantly on alpha adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction with minimal action on beta receptors. It functions as an oral nasal decongestant with minimal central nervous system (CNS) stimulation and it promotes sinus drainage. Guaifenesin is an expectorant which increases the output of phlegm (sputum) and bronchial secretions by reducing adhesiveness and surface tension. The increased flow of less viscid secretions promotes ciliary action and changes a dry, unproductive cough to one that is more productive and less frequent.

Indications and Usage
For the temporary relief of nasal congestion and dry nonproductive cough associated with the common cold, sinusitis, and other respiratory allergies. Helps drainage of the bronchial tubes by thinning the mucus.

Contraindications
This product is contraindicated in patients with known hypersensitivity to any of its ingredients. Also contraindicated in patients with severe hypertension, severe coronary artery disease and patients on monoamine oxidase (MAO) inhibitor therapy.

Warnings
This product should be prescribed with caution in patients with persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or where cough is accompanied by excessive secretions. Advise patients to take medication a few hours before bedtime to minimize the possibility of sleeplessness. The medication should be taken with a glass of water after each dose, to help loosen mucus in the lungs. Use with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes mellitus, narrow angle glaucoma or prostatic hypertrophy.

Precautions
Information for patients: Patients should be warned not to use this product if they are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If patients are uncertain whether a prescription drug contains an MAOI, they should be instructed to consult a health professional before taking such a product.

Drug interactions: MAO inhibitors may prolong and intensify the overall effects of sympathomimetic agents.

Carcinogenesis, mutagenesis, impairment of fertility: No long-term animal studies have been performed with this product.

Pregnancy: Teratogenic effects: Pregnancy Category C. Animal reproductive studies have not been conducted with this product. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be given to a pregnant woman only if clearly needed.

Nursing mothers: This product should not be administered to a nursing woman.

Geriatrics: Phenylephrine should be used with caution in the elderly because they may be more sensitive to the effects of sympathomimetics.

Laboratory test interactions: Guaifenesin or its metabolites may cause color interference with the VMA (vanillylmandelic acid) test for catechols. It may also falsely elevate the level of urinary 5-HIAA (5-hydroxyindoleacetic acid) in certain serotonin metabolite chemical tests because of color interference.

Adverse Reactions
Adverse reactions associated with phenylephrine may include nervousness, restlessness and headache. Serious side effects with sympathomimetics have been rare. Guaifenesin is well tolerated and has a wide margin of safety. Side effects have been generally mild and infrequent. Nausea and vomiting are the side effects that occur most commonly. Dizziness, headache, and rash (including urticaria) have been reported rarely.

Overdosage
Signs & symptoms: CNS stimulation (restlessness to convulsions).
Treatment: Induce vomiting if it has not occurred spontaneously. Precautions must be taken against aspiration especially in infants, children and comatose patients. If gastric lavage is indicated, isotonic or half-isotonic saline solution is preferred. Stimulants should not be used. Treatment is symptomatic and supportive. The acute toxicity of guaifenesin is low and overdosage is unlikely to produce serious toxic effects. In laboratory animals, no toxicity resulted when guaifenesin was administered by stomach tube in doses up to 5 grams/kg.

Dosage and Administration
Administer the recommended dose every 12 hours.

SINA-12X Suspension: *Children — over six years of age* — 5 to 10 mL (1 to 2 teaspoonfuls); *Children two to six years of age* — 2.5 to 5 mL (1/2 to 1 teaspoonful); *Children under two years of age* — Titrate dose individually.

How Supplied
SINA-12X Suspension (phenylephrine tannate 5 mg, and guaifenesin 100 mg per 5 mL): purple with grape flavor. The suspension is available in 4 ounce bottles (NDC 0037-6302-04).
Storage: Store at controlled room temperature 20°-25°C (68°-77°F).

U.S. Patent 6,462,094

Produced under license from
JFC Technologies
Bound Brook, NJ, U.S.A.
U.S. Patent 5,599,846

MedPointe pharmaceuticals
MedPointe Healthcare Inc.
Somerset, New Jersey 08873

Printed in U.S.A.

Rev. 1/03

SINA-12X
Tablets

IN-6301-01 Rev. 4/03

Description
SINA-12X is a nasal decongestant/expectorant available for oral administration as a tablet.
Each tablet contains:

Phenylephrine Tannate	25 mg
Guaifenesin	200 mg

Other ingredients: dibasic calcium phosphate, FD&C Blue No. 1, FD&C Red No. 40, magnesium stearate, methylcellulose, polygalacturonic acid, povidone, silicon dioxide, starch, talc.

Clinical Pharmacology
Phenylephrine is a sympathomimetic nasal decongestant which acts predominantly on alpha adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction with minimal action on beta receptors. It functions as an oral nasal decongestant with minimal central nervous system (CNS) stimulation and it promotes sinus drainage. Guaifenesin is an expectorant which increases the output of phlegm (sputum) and bronchial secretions by reducing adhesiveness and surface tension. The increased flow of less viscid secretions promotes ciliary action and changes a dry, unproductive cough to one that is more productive and less frequent.

Indications and Usage
For the temporary relief of nasal congestion and dry nonproductive cough associated with the common cold, sinusitis, and other respiratory allergies. Helps drainage of the bronchial tubes by thinning the mucus.

Contraindications
This product is contraindicated in patients with known hypersensitivity to any of its ingredients. Also contraindicated in patients with severe hypertension, severe coronary artery disease and patients on monoamine oxidase (MAO) inhibitor therapy.

Warnings
This product should be prescribed with caution in patients with persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or where cough is accompanied by excessive secretions. Advise patients to take medication a few hours before bedtime to minimize the possibility of sleeplessness. The medication should be taken with a glass of water after each dose, to help loosen mucus in the lungs. Use with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes mellitus, narrow angle glaucoma or prostatic hypertrophy.

Precautions
Information for patients: Patients should be warned not to use this product if they are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If patients are uncertain whether a prescription drug contains an MAOI, they should be instructed to consult a health professional before taking such a product.

Drug interactions: MAO inhibitors may prolong and intensify the overall effects of sympathomimetic agents.

Carcinogenesis, mutagenesis, impairment of fertility: No long-term animal studies have been performed with this product.

Pregnancy: Teratogenic effects: Pregnancy Category C. Animal reproductive studies have not been conducted with this product. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be given to a pregnant woman only if clearly needed.

Nursing mothers: This product should not be administered to a nursing woman.

Geriatrics: Phenylephrine should be used with caution in the elderly because they may be more sensitive to the effects of sympathomimetics.

Laboratory test interactions: Guaifenesin or its metabolites may cause color interference with the VMA (vanillylmandelic acid) test for catechols. It may also falsely elevate the level of urinary 5-HIAA (5-hydroxyindoleacetic acid) in certain serotonin metabolite chemical tests because of color interference.

Adverse Reactions
Adverse reactions associated with phenylephrine may include nervousness, restlessness and headache. Serious side effects with sympathomimetics have been rare. Guaifenesin is well tolerated and has a wide margin of safety. Side effects have been generally mild and infrequent. Nausea and vomiting are the side effects that occur most commonly. Dizziness, headache, and rash (including urticaria) have been reported rarely.

Overdosage
Signs & symptoms: CNS stimulation (restlessness to convulsions).
Treatment: Induce vomiting if it has not occurred spontaneously. Precautions must be taken against aspiration especially in infants, children and comatose patients. If gastric lavage is indicated, isotonic or half-isotonic saline solution is preferred. Stimulants should not be used. Treatment is symptomatic and supportive. The acute toxicity of guaifenesin is low and overdosage is unlikely to produce serious toxic effects. In laboratory animals, no toxicity resulted when guaifenesin was administered by stomach tube in doses up to 5 grams/kg.

Dosage and Administration
Administer the recommended dose every 12 hours.
SINA-12X Tablets: Adults and children 12 years of age and older — 1 or 2 tablets. Children 6 to 11 years — 1/2 or 1 tablet.

How Supplied
SINA-12X Tablets (phenylephrine tannate 25 mg, guaifenesin 200 mg): purple-colored, capsule-shaped, scored on one side and imprinted SINA 6301 on the other side. The tablets are available in bottles of 30 (NDC 0037-6301-03) and in bottles of 100 (NDC 0037-6301-10).
Storage: Store at controlled room temperature 20°-25°C (68°-77°F). Protect from moisture. Dispense in a tight container.

U.S. Patent 6,462,094

Produced under license from
JFC Technologies
Bound Brook, NJ, U.S.A.
U.S. Patent 5,599,846

Manufactured by:
Pharmaceutical Manufacturing Research Services, Inc. Horsham, PA 19044

Printed in U.S.A.

Distributed by:
MedPointe pharmaceuticals
MedPointe Healthcare Inc.
Somerset, New Jersey 08873

Rev. 4/03

RYNA®-12X
Suspension

IN-1809-01 Rev. 5/03

Description

RYNA®-12X is an antihistamine/nasal decongestant/expectorant available for oral administration as a *Suspension.*

Each 5 mL (one teaspoonful) of the blue-colored, grape-flavored suspension contains:

Phenylephrine Tannate	5 mg
Pyrilamine Tannate	30 mg
Guaifenesin	100 mg

Other ingredients: benzoic acid, FD&C Blue No. 1, FD&C Red No. 40, flavors (natural and artificial), glycerin, kaolin, magnesium aluminum silicate, methylparaben, pectin, purified water, saccharin sodium, sucrose.

Clinical Pharmacology

Phenylephrine is a sympathomimetic nasal decongestant which acts predominantly on alpha adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction with minimal action on beta receptors. It functions as an oral nasal decongestant with minimal central nervous system (CNS) stimulation and it promotes sinus drainage. Pyrilamine provides antihistaminic action. Guaifenesin is an expectorant which increases the output of phlegm (sputum) and bronchial secretions by reducing adhesiveness and surface tension. The increased flow of less viscid secretions promotes ciliary action and changes a dry, unproductive cough to one that is more productive and less frequent.

Indications and Usage

This product is indicated for the temporary, symptomatic relief of the coryza, nasal congestion and dry nonproductive cough associated with the common cold, sinusitis, and other respiratory allergies. Appropriate therapy should be provided for the primary disease. Helps drainage of the bronchial tubes by thinning the mucus.

Contraindications

This product is contraindicated in patients with known hypersensitivity to any of it ingredients. Also contraindicated in patients with severe hypertension, severe coronary artery disease, and patients on monoamine oxidase (MAO) inhibitor therapy.

Warnings

This product should be prescribed with caution in patients with persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or where cough is accompanied by excessive secretions. Advise patients to take medication a few hours before bedtime to minimize the possibility of sleeplessness. The medication should be taken with a glass of water after each dose, to help loosen mucus in the lungs. Use with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes mellitus, narrow angle glaucoma or prostatic hypertrophy.

Precautions

General: Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly patients. Antihistamines may cause excitation, particularly in children, but their combination with sympathomimetics may cause either mild stimulation or mild sedation.

Information for patients: Caution patients against drinking alcoholic beverages or engaging in potentially hazardous activities requiring alertness, such as driving a car or operating machinery, while using this product. Patients should be warned not to use these products if they are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If patients are uncertain whether a prescription drug contains an MAOI, they should be instructed to consult a health professional before taking such a product.

Drug Interactions: MAO inhibitors may prolong and intensify the anticholinergic effects of antihistamines and the overall effects of sympathomimetic agents.

Carcinogenesis, mutagenesis, impairment of fertility: No long term animal studies have been performed with this product.

Pregnancy: Teratogenic effects: Pregnancy Category C. Animal reproduction studies have not been conducted with this product. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be given to a pregnant woman only if clearly needed.

Nursing mothers: This product should not be administered to a nursing woman.

Geriatrics: Phenylephrine should be used with caution in the elderly because they may be more sensitive to the effects of sympathomimetics.

Laboratory test interactions: Guaifenesin or its metabolites may cause color interference with the VMA (vanillylmandelic acid) test for catechols. It may also falsely elevate the level of urinary 5-HIAA (5-hydroxyindoleacetic acid) in certain serotonin metabolite chemical tests because of color interference.

Adverse Reactions

Adverse effects associated with phenylephrine may include nervousness, restlessness, and headache. Adverse effects associated with antihistamines may include drowsiness, sedation, dryness of mucous membranes, and gastrointestinal effects. Serious side effects with oral antihistamines or sympathomimetics have been rare. Guaifenesin is well tolerated and has a wide margin of safety. Side effects have been generally mild and infrequent. Nausea and vomiting are the side effects that occur most commonly. Dizziness, headache, and rash (including urticaria) have been reported rarely.

Overdosage

Signs & symptoms: May vary from CNS depression to stimulation (restlessness to convulsions). Antihistamine overdosage in young children may lead to convulsions and death. Atropine-like signs and symptoms may be prominent.

Treatment: Induce vomiting if it has not occurred spontaneously. Precautions must be taken against aspiration especially in infants, children and comatose patients. If gastric lavage is indicated, isotonic or half-isotonic saline solution is preferred. Stimulants should not be used. If hypotension is a problem, vasopressor agents may be considered. The acute toxicity of guaifenesin is low and overdosage is unlikely to produce serious toxic effects. In laboratory animals, no toxicity resulted when guaifenesin was administered by stomach tube in doses up to 5 grams/kg.

Dosage and Administration

Administer the recommended dose every 12 hours.

RYNA®-12X Suspension: *Children over six years of age* - 5 to 10 mL (1 to 2 teaspoonfuls); *Children two to six years of age* - 2.5 to 5 mL (1/2 to 1 teaspoonful); *Children under two years of age* - Titrate dose individually.

How Supplied

RYNA®-12X Suspension (phenylephrine tannate 5 mg, pyrilamine tannate 30 mg and guaifenesin 100 mg per 5 mL): blue with grape flavor. The suspension is available in a 4 fl oz unit of use container with a 10 mL graduated oral syringe and fitment (NDC 0037-1809-04).

Storage: RYNA®-12X Suspension - Store at controlled room temperature 20°-25°C (68°-77°F).

Patent Pending

Produced under license from
JFC Technologies
Bound Brook, NJ, U.S.A.
U.S. Patent 5,599,846; 5,663,415

Printed in U.S.A.

medPointe pharmaceuticals
medPointe Healthcare Inc.
Somerset, New Jersey 08873
Rev. 5/03

RYNA®-12X
Tablets
IN-1708-01 Rev. 5/03

Description
RYNA®-12X is an antihistamine/nasal decongestant/expectorant available for oral administration as *Tablets* . Each tablet contains:

Phenylephrine Tannate	25 mg
Pyrilamine Tannate	60 mg
Guaifenesin	200 mg

Other ingredients: dibasic calcium phosphate, FD&C Blue No. 1, FD&C Red No. 40, magnesium stearate, methylcellulose, microcrystalline cellulose, polygalacturonic acid, silicon dioxide, talc.

Clinical Pharmacology
Phenylephrine is a sympathomimetic nasal decongestant which acts predominantly on alpha adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction with minimal action on beta receptors. It functions as an oral nasal decongestant with minimal central nervous system (CNS) stimulation and it promotes sinus drainage. Pyrilamine provides antihistaminic action. Guaifenesin is an expectorant which increases the output of phlegm (sputum) and bronchial secretions by reducing adhesiveness and surface tension. The increased flow of less viscid secretions promotes ciliary action and changes a dry, unproductive cough to one that is more productive and less frequent.

Indications and Usage
This product is indicated for the temporary, symptomatic relief of the coryza, nasal congestion and dry nonproductive cough associated with the common cold, sinusitis, and other respiratory allergies. Appropriate therapy should be provided for the primary disease. Helps drainage of the bronchial tubes by thinning the mucus.

Contraindications
This product is contraindicated in patients with known hypersensitivity to any of it ingredients. Also contraindicated in patients with severe hypertension, severe coronary artery disease, and patients on monoamine oxidase (MAO) inhibitor therapy.

Warnings
This product should be prescribed with caution in patients with persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or where cough is accompanied by excessive secretions. Advise patients to take medication a few hours before bedtime to minimize the possibility of sleeplessness. The medication should be taken with a glass of water after each dose, to help loosen mucus in the lungs. Use with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes mellitus, narrow angle glaucoma or prostatic hypertrophy.

Precautions
General: Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly patients. Antihistamines may cause excitation, particularly in children, but their combination with sympathomimetics may cause either mild stimulation or mild sedation.

Information for patients: Caution patients against drinking alcoholic beverages or engaging in potentially hazardous activities requiring alertness, such as driving a car or operating machinery, while using this product. Patients should be warned not to use these products if they are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If patients are uncertain whether a prescription drug contains an MAOI, they should be instructed to consult a health professional before taking such a product.

Drug Interactions: MAO inhibitors may prolong and intensify the anticholinergic effects of antihistamines and the overall effects of sympathomimetic agents.

Carcinogenesis, mutagenesis, impairment of fertility: No long term animal studies have been performed with this product.

Pregnancy: Teratogenic effects: Pregnancy Category C. Animal reproduction studies have not been conducted with this product. It is also not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be given to a pregnant woman only if clearly needed.

Nursing mothers: This product should not be administered to a nursing woman.

Geriatrics: Phenylephrine should be used with caution in the elderly because they may be more sensitive to the effects of sympathomimetics.

Laboratory test interactions: Guaifenesin or its metabolites may cause color interference with the VMA (vanillylmandelic acid) test for catechols. It may also falsely elevate the level of urinary 5-HIAA (5-hydroxyindoleacetic acid) in certain serotonin metabolite chemical tests because of color interference.

Adverse Reactions

Adverse effects associated with phenylephrine may include nervousness, restlessness, and headache. Adverse effects associated with antihistamines may include drowsiness, sedation, dryness of mucous membranes, and gastrointestinal effects. Serious side effects with oral antihistamines or sympathomimetics have been rare. Guaifenesin is well tolerated and has a wide margin of safety. Side effects have been generally mild and infrequent. Nausea and vomiting are the side effects that occur most commonly. Dizziness, headache, and rash (including urticaria) have been reported rarely.

Overdosage

Signs & symptoms: May vary from CNS depression to stimulation (restlessness to convulsions). Antihistamine overdosage in young children may lead to convulsions and death. Atropine-like signs and symptoms may be prominent.

Treatment: Induce vomiting if it has not occurred spontaneously. Precautions must be taken against aspiration especially in infants, children and comatose patients. If gastric lavage is indicated, isotonic or half-isotonic saline solution is preferred. Stimulants should not be used. If hypotension is a problem, vasopressor agents may be considered. The acute toxicity of guaifenesin is low and overdosage is unlikely to produce serious toxic effects. In laboratory animals, no toxicity resulted when guaifenesin was administered by stomach tube in doses up to 5 grams/kg.

Dosage and Administration

Administer the recommended dose every 12 hours.
RYNA®-12X Tablets: Adults and children 12 years of age and older - 1 or 2 tablets.
Children 6 to 11 years - 1/2 or 1 tablet.

How Supplied

RYNA®-12X Tablets (phenylephrine tannate 25 mg, pyrilamine tannate 60 mg and guaifenesin 200 mg): blue-colored, oval, scored on one side and imprinted RYNA 1708 on the other side. The tablets are available in bottles of 30 (NDC 0037-1708-03) and in bottles of 100 (NDC 0037-1708-10).

Storage: RYNA®-12X Tablets - Store at controlled room temperature 20°-25°C (68°-77°F).

Protect from moisture. Dispense in a tight container.

Patent Pending

Produced under license from
JFC Technologies
Bound Brook, NJ, U.S.A.
U.S. Patent 5,599,846; 5,663,415

RYNA®-12X Tablets are manufactured by:
Pharmaceutical Manufacturing Research Services, Inc. Horsham, PA 19044

Printed in U.S.A.

Distributed by:

MedPointe pharmaceuticals
MedPointe Healthcare Inc.
Somerset, New Jersey 08873

Rev. 5/03

TUSSI-12® D TUSSI-12® D S

Tablets Suspension

IN-0692-03 Rev. 4/03

Description

TUSSI-12D is an antitussive/antihistamine/nasal decongestant combination available for oral administration as Tablets and as a Suspension.

Each tablet contains:

Carbetapentane Tannate	60 mg
Pyrilamine Tannate	40 mg
Phenylephrine Tannate	10 mg

Other ingredients: corn starch, dibasic calcium phosphate, FD&C Blue No. 1, FD&C Red No. 40, magnesium stearate, methylcellulose, polygalacturonic acid, povidone, silicon dioxide, talc.

Each 5 mL (one teaspoonful) of the suspension contains:

Carbetapentane Tannate	30 mg
Pyrilamine Tannate	30 mg
Phenylephrine Tannate	5 mg

Other ingredients: benzoic acid, FD&C Blue No. 1, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5 (see Precautions), flavors (natural and artificial), glycerin, kaolin, magnesium aluminum silicate, methylparaben, pectin, purified water, saccharin sodium, sucrose.

Clinical Pharmacology

TUSSI-12D Tablets and TUSSI-12D S Suspension combine the antitussive action of carbetapentane, the sympathomimetic decongestant effect of phenylephrine, and the antihistaminic action of pyrilamine.

Indications and Usage

TUSSI-12D Tablets and TUSSI-12D S Suspension are indicated for the symptomatic relief of cough associated with respiratory tract conditions such as the common cold, bronchial asthma, acute and chronic bronchitis. Appropriate therapy should be provided for the primary disease.

Contraindications

TUSSI-12D Tablets and TUSSI-12D S Suspension are contraindicated for newborns, nursing mothers, and patients who are sensitive to any of the ingredients or related compounds.

Warnings

Use with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes, narrow angle glaucoma, or prostatic hypertrophy. Do not use in patients taking monoamine oxidase (MAO) inhibitors, or for 14 days after stopping treatment with an MAOI.

This product contains an antihistamine which may cause drowsiness and may have additive central nervous system (CNS) effects with alcohol or other CNS depressants (e.g., hypnotics, sedatives, tranquilizers).

Precautions

TUSSI-12D S Suspension contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

General: Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients. Antihistamines may cause excitation, particularly in children, but their combination with sympathomimetics may cause either mild stimulation or mild sedation.

Information for patients: Caution patients against drinking alcoholic beverages or engaging in potentially hazardous activities requiring alertness, such as driving a car or operating machinery, while using this product. Patients should be warned not to use this product if they are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If patients are uncertain whether a prescription drug contains an MAOI, they should be instructed to consult a health professional before taking such a product.

Drug Interactions: MAO inhibitors may prolong and intensify the anticholinergic effects of antihistamines and sympathomimetics.

Carcinogenesis, mutagenesis, impairment of fertility: No long term animal studies have been performed with TUSSI-12D Tablets or TUSSI-12D S Suspension.

Pregnancy: Teratogenic effects: Pregnancy Category C. Animal reproduction studies have not been conducted with TUSSI-12D Tablets or TUSSI-12D S Suspension. It is also not known whether TUSSI-12D Tablets or TUSSI-12D S Suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. TUSSI-12D Tablets or TUSSI-12D S Suspension should be given to a pregnant woman only if clearly needed.

Nursing mothers: TUSSI-12D Tablets or TUSSI-12D S Suspension should not be administered to a nursing woman.

Adverse Reactions

Adverse reactions may include drowsiness, sedation, dryness of mucous membranes, and gastrointestinal effects. Serious side effects with oral antihistamines or sympathomimetics have been rare.

Overdosage

Signs and symptoms: May vary from CNS depression to stimulation (restlessness to convulsions). Antihistamine overdosage in young children may lead to convulsions and death. Atropine-like signs and symptoms may be prominent.

Treatment: Induce vomiting if it has not occurred spontaneously. Precautions must be taken against aspiration especially in infants, children, and comatose patients. If gastric lavage is indicated, isotonic or half-isotonic saline solution is preferred. Stimulants should not be used. If hypotension is a problem, vasopressor agents may be considered.

TUSSI-12® D
Tablets

TUSSI-12® D S
Suspension

IN-0692-03 Rev. 4/03

Dosage and Administration
Administer the recommended dose every 12 hours.

TUSSI-12D Tablets: Adults and children 12 years and older — 1 to 2 tablets.
Children 6 to 11 years — 1/2 or 1 tablet.

TUSSI-12D S Suspension: *Over six years of age* — 5 to 10 mL (1 to 2 teaspoonfuls); *Children two to six years of age* — 2.5 to 5 mL (1/2 to 1 teaspoonful); *Children under two years of age* — Titrate dose individually.

How Supplied
TUSSI-12D Tablets are pink-colored, capsule-shaped, scored on one side and imprinted WALLACE 0692 on the other side, containing in each tablet: carbetapentane tannate 60 mg, pyrilamine tannate 40 mg, phenylephrine tannate 10 mg, available in bottles of 100 (NDC 0037-0692-10).

TUSSI-12D S Suspension is pink with strawberry-currant flavor, containing in each 5 mL (one teaspoonful): carbetapentane tannate 30 mg, pyrilamine tannate 30 mg, phenylephrine tannate 5 mg, available in 4 fl oz unit of use containers with a 10 mL graduated oral syringe and fitment (NDC 0037-0693-04).

Storage: Store at controlled room temperature 20°-25°C (68°-77°F).

Dispense in a tight container.

U.S. Patent 6,417,206
Produced under license from
JFC Technologies
Bound Brook, NJ, U.S.A.
U.S. Patents 5,599,846; 5,663,415

MedPointe pharmaceuticals
MedPointe Healthcare Inc.
Somerset, New Jersey 08873

Printed in U.S.A.

Rev. 4/03