10 Overdosage

No negative effects of an overdose have been reported and none are expected due to the homeopathic dilutions.

11 Description

11.1 **Ingredients**

• Each 2.2 ml ampule contains:

Active Ingredients:			
Ingredient name	Potency	Quantity	Final dilution
Aconitum napellus	2X	1.32 µl	5.22X
Arnica montana, radix	2X	2.20 µl	5.00X
Bellis perennis	2X	1.10 µl	5.30X
Belladonna	2X	2.20 µl	5.00X
Calendula officinalis	2X	2.20 µl	5.00X
Chamomilla	3X	2.20 µl	6.00X
Echinacea	2X	0.55 µl	5.60X
Echinacea purpurea	2X	0.55 µl	5.60X
Hamamelis virginiana	1X	0.22 µl	5.00X
Hepar sulphuris calcareum	6X	2.20 µl	9.00X
Hypericum perforatum	2X	0.66 µl	5.52X
Mercurius solubilis	6X	1.10 µl	9.30X
Millefolium	3X	2.20 µl	6.00X
Symphytum officinale	6X	2.20 µl	9.00X

Inactive Ingredients:

Water for injection 2,179.10 µl

Sodium Chloride 19.40 µl

11.2 **Pharmaceutical Form**

• Injection solution

11.3 **Route of Administration**

• Parenteral: s.c., i.d., i.m., i.a. or i.v

13 Clinical Pharmacology

13.1 **Mechanism of Action**

The exact mechanism of Traumeel® Injection Solution is not fully understood.

13.2 **Pharmacodynamics**

Not applicable for homeopathic medicinal products.

15 References

• Homeopathic Pharmacopeia of the United States Revision Service

16 How Supplied / Storage and handling

16.1 **Dosage forms and package sizes**

• 1 ampule of 2.2 ml in packs of 10 ampules

• NDC 50114-7004-1

16.2 **Storage and handling**

• Store at room temperature. Protect from light.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Traumeel® Injection Solution safely and effectively. See full prescribing information for Traumeel®.

Traumeel® Injection Solution, Parenteral Use Rx Only

-----INDICATIONS AND USAGE-----

Traumeel® Injection Solution is a homeopathic drug indicated:

- As a mono-therapy, for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain. (1.1)
- In combination with Zeel® Injection Solution, for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis / osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness. (1.2)

-----DOSAGE AND ADMINISTRATION------

- Standard Dosage:
  Adults and children 12 years and older:
  1 ampule 1 to 3 times per 7 days
  Children 6 to 11 years:
  ⅔ of an ampule 1 to 3 times per 7 days
  Children 2 to 5 years:
  ½ ampule 1 to 3 times per 7 days (2.2)
- Acute Dosage:
  Adults and children 12 years and older:
  1 ampule daily, and then continue with standard dosage.
  Children 6 to 11 years: ⅔ of an ampule daily, and then continue with standard dosage.
  Children 2 to 5 years: ½ ampule daily, and then continue with standard dosage. (2.3)
- When co-administered with Zeel® Injection Solution, the two products may be mixed 1:1.

-----DOSAGE FORM AND STRENGTH-----

- 1 ampule containing 2.2 ml each containing the active ingredients in the strengths listed under Description. (3)

------CONTRAINDICATIONS-----

- Traumeel® Injection Solution is contraindicated in patients with known hypersensitivity to Traumeel® or any of its ingredients. (4)

-----WARNINGS AND PRECAUTIONS-----

- Keep out of reach of children. (5)

-----ADVERSE REACTIONS------

- Allergic (hypersensitivity) reactions, (e.g. skin allergies, redness/swelling at the injection site, even up to anaphylaxis) may occur in isolated cases. (6)
- **To report SUSPECTED ADVERSE REACTIONS, contact MediNatura at 1.844.633.4628 or info@medinatura.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**.

-----DRUG INTERACTIONS-----

- None known (7)

-----USE IN SPECIFIC POPULATIONS-----

- No studies have been conducted with Traumeel® Injection Solution on pregnant or lactating women, children, or elderly. (8)

Revised 12/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

***** *Sections or subsections omitted from the full prescribing information are not listed.*

FULL PRESCRIBING INFORMATION

1 Indications and Usage

1.1 **Treatment of injuries and various conditions of the musculoskeletal system.**

- Traumeel® Injection Solution is a homeopathic drug product indicated for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.

1.2 **Co-administration Therapy with Zeel® Injection Solution for the treatment of inflammatory and degenerative conditions of the musculoskeletal system.**

- Traumeel® Injection Solution is a homeopathic drug product indicated, in combination with Zeel® Injection Solution, for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness.

2 Dosage and Administration

2.1 **General Considerations**

- The dosage schedules listed below can be used as a general guide for the administration of Traumeel® Injection Solution.
- If co-administration with a local anesthetic is desired, Traumeel® Injection Solution may be mixed with lidocaine or similar agents at the discretion of the physician.
- Traumeel® Injection solution may be administered s.c., i.d., i.m., i.a. or i.v.
- The interval between injections is left to the discretion of the HCP, but should not exceed 1 ampule in 24 hours.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Draw up the contents of the ampule into the syringe. Discard half or one third of the contents, depending on the required dosage, before administering.
- Only licensed practitioners with sufficient expertise in injecting drugs, including the respective route of administration, should administer the product.

2.2 **Standard Dosage** - for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.
Adults and children 12 years and older:
1 ampule 1 to 3 times per 7 days
Children 6 to 11 years:
⅔ of an ampule 1 to 3 times per 7 days
Children 2 to 5 years:
½ ampule 1 to 3 times per 7 days

2.3 **Acute Dosage** – for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.
Adults and children 12 years and older:
1 ampule daily, and then continue with standard dosage.
Children 6 to 11 years:
⅔ of an ampule daily, and then continue with standard dosage.
Children 2 to 5 years:
½ ampule daily, and then continue with standard dosage.

2.4 **Co-administration therapy with Zeel® Injection Solution** – for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness.

- In the treatment of musculoskeletal conditions, if co-administration with another homeopathic medicinal product is desired, Traumeel® Injection Solution may be mixed in a ratio of 1:1 with Zeel® Injection Solution.
- For convenience, the daily dose of Traumeel® Injection Solution may be administered at the same time as a Zeel® Injection Solution, according to the dosing recommendations for each medication.

2.5 **Instructions for Use**

- Cutting open the glass ampule is not necessary. Hold the ampule head up at an angle, and tap/shake down the solution contained in the ampule head. Then break off the ampule head by applying pressure away from the color dot. Discard unused solution.

3 Dosage Forms and Strength

One ampule containing 2.2 ml each containing the active ingredients in the strengths listed under Description. (11)

4 Contraindications

- Traumeel® Injection Solution is contraindicated in patients with known hypersensitivity to Traumeel® or any of its ingredients.
- When Traumeel® Injection Solution is co-administered with Zeel® Injection Solution , refer to the *Contraindications* section of the respective Zeel® Injection Solution labeling.

5 Warnings and Precautions

None.

6 Adverse Reactions

6.1 Post-marketing Experience

- The following adverse events have been identified during post-marketing use of Traumeel® Injection Solution. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
- Adverse event rates observed in Monotherapy use of Traumeel® Injection Solution: Allergic (hypersensitivity) reactions (e.g. skin allergies, redness/swelling at the injection site, even up to anaphylaxis) may occur in isolated cases.
- Adverse event rates observed in the Monotherapy use of Zeel® Injection Solution: Allergic (hypersensitivity) skin reactions may occur in isolated cases.

7 Drug Interactions

No interactions have been reported, and none are expected due to the homeopathic dilutions.

8 Use in Specific Populations

8.1 **Pregnancy**

8.1.1 Teratogenic effects

Pregnancy Category C. Some ingredients in Traumeel® Injection Solution have been shown to be teratogenic in various animal species when given in doses several thousand times the human dose. There are no adequate and well-controlled studies in pregnant women. Traumeel® Injection solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

When Traumeel® Injection Solution is administered with Zeel® Injection Solution in a woman of childbearing age, refer to the pregnancy category and product labelling for Zeel® Injection Solution.

8.1.2 Non-teratogenic effects

No known non-teratogenic effects.

8.2 **Labor and Delivery**

No recognized use in labor or delivery.

8.3 **Nursing Mothers:**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Traumeel® Injection Solution is administered to a nursing woman.

8.4 **Pediatric Use**

Safety and effectiveness in pediatric patients have not been established. However, traditional homeopathic use of the ingredients in Traumeel® Injection Solution has not identified differences in responses between adults and pediatric patients.

8.5 **Geriatric Use**

Safety and effectiveness in geriatric patients have not been established. However, traditional homeopathic use of the of the ingredients in Traumeel® Injection Solution has not identified differences in responses between adults and geriatric patients.

10 Overdosage

No negative effects of an overdose have been reported and none are expected due to the homeopathic dilutions.

11 Description

11.1 **Ingredients**

• Each 2.0 ml ampule contains:

Active Ingredients:			
Ingredient name	Potency	Quantity	Final dilution
a-Lipoicum acidum	8X	2.0 µl	10.99X
Arnica montana, radix	4X	200.0 µl	5.00X
Cartilago suis	6X	2.0 µl	9.00X
Coenzyme A	8X	2.0 µl	10.99X
Dulcamara	3X	10.0 µl	5.30X
Embryo totalis suis	6X	2.0 µl	9.00X
Funiculus umbilicalis suis	6X	2.0 µl	9.00X
Nadidum	8X	2.0 µl	10.99X
Natrum oxalaceticum	8X	2.0 µl	10.99X
Placenta suis	6X	2.0 µl	9.00X
Rhus toxicodendron	2X	10.0 µl	4.30X
Sanguinaria canadensis	4X	3.0 µl	6.82X
Sulphur	6X	3.6 µl	8.74X
Symphytum officinale	6X	10.0 µl	8.30X

Inactive Ingredients:
Water for injection 1,747.4 µl
Sodium chloride 17.6 µl

11.2 **Pharmaceutical Form**

• Sterile injection solution

11.3 **Route of Administration**

• Parenteral: s.c., i.d., i.m., i.a. or i.v

12 Clinical Pharmacology

12.1 **Mechanism of Action**

The exact mechanism of Zeel® Injection Solution is not fully understood.

12.2 **Pharmacodynamics**

Not applicable for homeopathic medicinal products.

13 References

• Homeopathic Pharmacopeia of the United States Revision Service

14 How Supplied / Storage and handling

14.1 **Dosage forms and package sizes**

• 1 ampule of 2.0 ml in packs of 10
• NDC 50114-7030-1

14.2 **Storage and handling**

• Store at room temperature. Protect from light.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Zeel® Injection Solution safely and effectively. See full prescribing information for Zeel®.

Zeel® Injection Solution, Parenteral Use Rx Only

-----INDICATIONS AND USAGE-----

Zeel® Injection Solution is a homeopathic drug indicated:

- As a mono-therapy, for the treatment of arthrosis/ osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness. (1.1)
- In combination with Traumeel® Injection Solution, for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis /osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness. (1.2)

-----DOSAGE AND ADMINISTRATION-----

- Standard Dosage:
  Adults and children 12 years and older:
  1 ampule 1 to 3 times per 7 days
  Children 6 to 11 years:
  ⅔ of an ampule 1 to 3 times per 7 days (2.2)
- Acute Dosage:
  Adults and children 12 years and older:
  1 ampule daily, and then continue with standard dosage.
  Children 6 to 11 years:
  ⅔ of an ampule daily, and then continue with standard dosage. (2.3)
- When co-administered with Traumeel® Injection Solution, the two products may be mixed 1:1.

-----DOSAGE FORM AND STRENGTH-----

- 1 ampule containing 2.0 ml each containing the active ingredients in the strengths listed under Description. (10.3)

-----CONTRAINDICTIONS-----

- Zeel® Injection Solution is contraindicated in patients with known hypersensitivity to Zeel® or any of its ingredients. (4)

-----WARNINGS AND PRECAUTIONS-----

- Keep out of reach of children. (5)

-----ADVERSE REACTIONS-----

- Allergic (hypersensitivity) skin reactions may occur in isolated cases. (6)
- **To report SUSPECTED ADVERSE REACTIONS, contact MediNatura. at 1.844.633.4628 or info@medinatura.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**.

-----DRUG INTERACTIONS-----

- None known (7)

-----USE IN SPECIFIC POPULATIONS-----

- No studies have been conducted with Zeel® Injection Solution on pregnant or lactating women, children, or elderly. (8) **Revised 12/2014**

FULL PRESCRIBING INFORMATION: CONTENTS*

* *Sections or subsections omitted from the full prescribing information are not listed.*

FULL PRESCRIBING INFORMATION

1 Indications and Usage

1.1 **Treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases**

- Zeel® Injection Solution is a homeopathic drug product indicated for the treatment of arthrosis/ osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.

1.2 **Co-administration Therapy with Traumeel® Injection Solution for the treatment of inflammatory and degenerative conditions of the musculoskeletal system.**

- Zeel® Injection Solution is a homeopathic drug product indicated, in combination with Traumeel® Injection Solution, for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness.

2 Dosage and Administration

2.1 **General Considerations**

- The dosage schedules listed below can be used as a general guide for the administration of Zeel® Injection Solution.
- If co-administration with a local anesthetic is desired, Zeel® Injection Solution may be mixed with lidocaine or similar agents at the discretion of the physician.
- Zeel® Injection solution may be administered s.c., i.d., i.m., i.a. or i.v.
- The interval between injections is left to the discretion of the HCP, but should not exceed 1 ampule in 24 hours.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Draw up the contents of the ampule into the syringe. Discard half or one third of the contents, depending on the required dosage, before administering
- Only licensed practitioners with sufficient expertise in injecting drugs, including the respective route of administration, should administer the product.

2.2 **Standard Dosage** - for the treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.
Adults and children 12 years and older:
1 ampule 1 to 3 times per 7 days
Children 6 to 11 years:
⅔ of an ampule 1 to 3 times per 7 days

2.3 **Acute Dosage** – for the treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness.
Adults and children 12 years and older:
1 ampule daily, and then continue with standard dosage.
Children 6 to 11 years:
⅔ of an ampule daily, and then continue with standard dosage.

2.4 **Co-administration therapy with Traumeel® Injection Solution** – for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness.

- In the treatment of musculoskeletal conditions, if co-administration with another homeopathic medicinal product is desired, Zeel® Injection Solution may be mixed in a ratio of 1:1 with Traumeel® Injection Solution.
- For convenience, the daily dose of Zeel® Injection Solution may be administered at the same time as a Traumeel® Injection Solution, according to the dosing recommendations for each medication.

2.5 

- Cutting open the glass ampule is not necessary. Hold the ampule head up at an angle, and tap/shake down the solution contained in the ampule head. Then break off the ampule head by applying pressure away from the color dot. Discard unused solution.

3 Dosage Forms and Strength

One ampule containing 2.0 ml each containing the active ingredients in the strengths listed under Description. (11)

4 Contraindications

- Zeel® Injection Solution is contraindicated in patients with known hypersensitivity to Zeel® or any of its ingredients.
- When Zeel® Injection Solution is co-administered with Traumeel® Injection Solution, refer to the *Contraindications* section of the respective Traumeel® Injection Solution labeling.

5 Warnings and Precautions

None.

6 Adverse Reactions

6.1 Post-marketing Experience

- The following adverse events have been identified during post-marketing use of Zeel® Injection Solution. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
- Adverse event rates observed in Monotherapy use of Zeel® Injection Solution: Allergic (hypersensitivity) skin reactions may occur in isolated cases.
- Adverse event rates observed in Monotherapy use of Traumeel® Injection Solution: Allergic (hypersensitivity) reactions (e.g. skin allergies, redness/swelling at the injection site, even up to anaphylaxis) may occur in isolated cases.

7 Drug Interactions

No interactions have been reported, and none are expected due to the homeopathic dilutions.

8 Use in Specific Populations

8.1 **Pregnancy**

8.1.1 Teratogenic effects

Pregnancy Category C. Some ingredients in Zeel® Injection Solution have been shown to be teratogenic in various animal species when given in doses several thousand times the human dose. There are no adequate and well-controlled studies in pregnant women. Zeel® Injection solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

When Zeel® Injection Solution is administered with Traumeel® Injection Solution in a woman of childbearing age, refer to the pregnancy category and product labelling for Traumeel® Injection Solution.

8.1.2 Non-teratogenic effects

No known non-teratogenic effects.

8.2 **Labor and delivery**

No recognized use in labor or delivery.

8.3 **Nursing Mothers:**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Zeel® Injection Solution is administered to a nursing woman.

8.4 **Pediatric use**

Safety and effectiveness in pediatric patients have not been established. However, traditional homeopathic use of the ingredients in Zeel® Injection Solution has not identified differences in responses between adults and pediatric patients.

8.5 **Geriatric use**

Safety and effectiveness in geriatric patients have not been established. However, traditional homeopathic use of the ingredients in Zeel® Injection Solution has not identified differences in responses between adults and geriatric patients.