

**INDICATIONS AND USAGE**

Terazosin capsules are indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH).

There is a rapid response, with approximately 70% of patients experiencing an increase in urinary flow rate in the first few hours after dosing. During the first 3 hours after dosing 12.5% of patients had a threshold response (flow rate greater than 15 mL/s at 30 minutes) and 3.8% of the patients had a threshold response (flow rate greater than 20 mL/s at 30 minutes).

**CONTRAINdications**

Terazosin capsules are contraindicated in patients known to be hypersensitive to terazosin or any component of the formulation.

**WARNINGS**

*Sympathetic “Vaso-dose” Effect*

Terazosin capsules, like other alpha-adrenergic blocking agents, can cause marked lowering of blood pressure, especially postural hypotension, and syncope in association with the first dose or a slight dose increase of therapy. A similar effect can be anticipated if therapy is interrupted for several days and restarted or increased.

Alpha-blockers in animals cause a decrease in blood pressure by decreasing total peripheral vascular resistance. The surmountable hypotensive action of terazosin appears to be produced mainly by blockade of alpha 1-adrenoceptors. Terazosin decreases blood pressure gradually within 15 minutes following oral administration.

Prostatic Cancer

General

**PRECAUTIONS**

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**Pharmacokinetics**

**B. Hypertension**

In animals, terazosin causes a decrease in blood pressure by decreasing total peripheral vascular resistance. The surmountable hypotensive action of terazosin appears to be produced mainly by blockade of alpha 1-adrenoceptors. Terazosin decreases blood pressure gradually within 15 minutes following oral administration.

**Pharmacodynamics**

**B. Hypertension**

In multiple dose clinical trials involving nearly 2000 hypertensive patients treated with terazosin capsules, respectively.

**OTHER**

The greater blood pressure effect associated with peak plasma concentration (first few hours after dosing) appears somewhat more prominent than the effect of the minimum dose of 1 mg of terazosin for 1 hour, and the average plasma levels of terazosin in plasma was about 10 mg/mL at a dose of 1 mg and 15 mg/mL at a dose of 5 mg. The effect of terazosin on blood pressure was greatest during the first 2 weeks of therapy, and then gradually decreased over the next 8 weeks. The effect of terazosin on blood pressure was greater in patients with a higher baseline blood pressure.

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**Pharmacokinetics**

In three placebo-controlled BPH studies 1, 2, and 3 (see CLINICAL PHARMACOLOGY), the incidence of post-dose syncope and syncope in association with the first dose or a slight dose increase of therapy. A similar effect can be anticipated if therapy is interrupted for several days and restarted or increased.

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Carcinomas of the prostate and BPH cause many of the same symptoms. These two diseases frequently co-exist. Therefore, patients thought to have BPH should be examined prior to starting terazosin capsule therapy to rule out the presence of carcinoma of the prostate.

Impotency Flurry 60 Syndromes (EHS)

Impotency Flurry 60 Syndrome (EHS) has been observed during cataract surgery in some patients who have previously received alpha blockers. This variation of small pupil syndrome is characterized by the combination of a fibrin clot that closes the inferotemporal iridectomy, progressive impotency synchiae into preoperative dilatation with limited mydriatic drugs, and potential prolapse of the iris into the posterior chamber with cataract. The patient's edema is usually present in the peripheral iris, and a cataract is often observed during surgery. There does not appear to be a benefit of stopping alpha blocker therapy prior to surgery.

Orthostatic Hypotension

While cataract surgery is the most severe orthostatic effect of terazosin (see WARNINGS) other symptoms of lowered blood pressure, such as dizziness, lightheadedness, and palpitations, were more common and occurred in some 20% of patients in clinical trials of hypertension. In EHS clinical trials, 20% of the patients experienced one or more of the following: dizziness, hypotension, postural hypotension, syncope, and tachycardia. Patients with occupations in which such events are potential problems should be treated with particular caution.

Information for Patients (see Package Insert)

Patients should be made aware of the possibility of syncope and orthostatic symptoms, especially at the initiation of therapy, and at the initiation of escalation of doses for 2-3 days after the dose has been increased, and after initiation of therapy when treatment is resumed. If they become aware of the occurrence of symptoms suggestive of cardiovascular collapse, they should also be advised to be on the lookout for syncope when symptoms of lowered blood pressure occur, although these symptoms are usually transient, and be less likely when symptoms of syncope or bradycardia are observed.

Laboratory Tests

Small but statistically significant increases in serum creatinine, hemoglobin, white blood cells, and alanine and aspartate aminotransferases were observed in controlled clinical trials. These laboratory changes suggest the possibility of hemodilution. Treatment with terazosin capsules for age 24 months had no significant effects on prostatic specific antigen (PSA) levels.

Drug Interactions

In controlled trials, no adverse effects on the incidence of treatment-related adverse events were observed. Terazosin has been coadministered in patients who had been on antihypertensive agents, including diuretics, beta blockers, calcium channel blockers, and other antihypertensive drugs, and their combination. The concomitant administration of terazosin and captopril was not associated with increased cardiovascular events. Terazosin has also been coadministered with the alpha blocker, Minipress®, another (marketed) selective-alpha-1 blocking agent.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Terazosin was devoid of mutagenic potential when evaluated in vivo and in the Ames test, in Chinese hamster osteosarcoma cells and the forward mutation assay, of increased linearly with dose at steady-state after administration of terazosin plus captopril (see DOSAGE AND ADMINISTRATION). The absence of mutagenicity in a battery of tests, of increased tumor incidences in both species) were most likely secondary to maternal toxicity. There are no adequate and

DOSAGE AND ADMINISTRATION

In a study (n=24) where terazosin and verapamil were administered concomitantly, terazosin’s mean ($\pm$ S.D.) total plasma level increased 4.7 fold ($\pm$ 1.8 fold) from 93 to 350 mg/mL for those patients that had not been on verapamil treatment. In 13 patients that had been on 300 mg verapamil for 30 days, terazosin was administered at steady-state in doses ranging from 1 to 20 mg per day. Plasma terazosin levels were increased 2.4 fold ($\pm$ 1.5 fold) from 23 to 60 mg/mL for those patients that had been on verapamil treatment. The effect of terazosin on fertility was assessed in a standard fertility/reproductive performance study in which male and female rats were administered oral doses of 8, 30 and 120 mg/kg/day. Four of 20 females were pregnant in the control group, and none of the females were pregnant in the terazosin group. The effect on fertility was assessed in a standard fertility/reproductive performance study in which male and female rats were administered oral doses of 8, 30 and 120 mg/kg/day. Four of 20 females were pregnant in the control group, and none of the females were pregnant in the terazosin group. The effect of terazosin on fertility was assessed in a standard fertility/reproductive performance study in which male and female rats were administered oral doses of 8, 30 and 120 mg/kg/day. Four of 20 females were pregnant in the control group, and none of the females were pregnant in the terazosin group. The effect of terazosin on fertility was assessed in a standard fertility/reproductive performance study in which male and female rats were administered oral doses of 8, 30 and 120 mg/kg/day. Four of 20 females were pregnant in the control group, and none of the females were pregnant in the terazosin group.

Use With Other Drugs

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Additional adverse reactions have been reported, but these are, in general, not distinguishable from symptoms that might have occurred in the absence of exposure to terazosin. The safety profile of patients treated in long-term open-label study was similar to that observed in the controlled studies.

The adverse events were usually transient and mild or moderate in intensity, but sometimes were serious enough to require medical intervention. The placebo-controlled clinical trials, in some instances, were not randomly different from the placebo and terazosin groups. The adverse events that were bothersome, as judged by their being reported as reasons for discontinuation due to adverse events were not statistically different between the placebo and terazosin groups. The adverse events were usually transient and mild or moderate in intensity, but sometimes were serious enough to require medical intervention. The placebo-controlled clinical trials, in some instances, were not randomly different from the placebo and terazosin groups. The adverse events that were bothersome, as judged by their being reported as reasons for discontinuation due to adverse events were not statistically different between the placebo and terazosin groups. 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symptom that might have occurred in the absence of treatment. The following additional adverse reactions were reported by at least 1% of 1,987 patients who received terazosin controlled-release, short- or long-term clinical trials or have been reported during marketing experience:

- Headache
- Chest pain, facial edema, lower abdominal pain, neck pain, ankle pain.

**Cardiovascular System**
- Arthralgia, rash, tachycardia.

**Gastrointestinal System**
- Abdominal pain, gastrointestinal disorders.

**Musculoskeletal System**
- Arthritis, joint pain, myalgia.

**Nervous System**
- Anxiety, insomnia.

**Respiratory System**
- Bronchitis, cold symptoms, eumonia, flu symptoms, increased cough, pharyngitis, rhinitis.

**Skin and Appendages**
- Pruritus, rash, sweating.

**Special Senses**
- Abnormally vision, conjunctivitis, rhinitis.

**Genitourinary System**
- Urinary frequency, urinary incontinence primarily reported in postmenopausal women, urinary tract infection.

The adverse reactions were usually mild to moderate in intensity but sometimes were severe enough to require treatment. The adverse reactions that were most bothersome, as judged by the patient, are listed as reasons for discontinuation of therapy by at least 0.5% of the terazosin group, and being reported more often than in the placebo group, are shown in Table 4.

### TABLE 4. Discontinuations During Placebo-Controlled Trials: Hypertension

<table>
<thead>
<tr>
<th>Body System</th>
<th>Terazosin (N = 269)</th>
<th>Placebo (N = 269)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BODY AS A WHOLE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal</td>
<td>1.5%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Migraine</td>
<td>1.7%</td>
<td>1.0%</td>
</tr>
<tr>
<td><strong>CARDIOVASCULAR SYSTEM</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bradycardia</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.2%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Palpitations</td>
<td>0.6%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>0.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td><strong>DIGESTIVE SYSTEM</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td><strong>METABOLIC AND NUTRITIONAL DISORDERS</strong></td>
<td></td>
<td></td>
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<tr>
<td>Peripheral Edema</td>
<td>0.6%</td>
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<tr>
<td><strong>NERVOUS SYSTEM</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>3.5%</td>
<td>0.4%</td>
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<tr>
<td>Depression</td>
<td>0.8%</td>
<td>0.2%</td>
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<tr>
<td>Insomnia</td>
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<tr>
<td><strong>RESPIRATORY SYSTEM</strong></td>
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<tr>
<td>Dyspnea</td>
<td>0.9%</td>
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<tr>
<td>Nasal Congestion</td>
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<td><strong>SPECIAL SENSES</strong></td>
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<td>Blurred Vision</td>
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<tr>
<td><strong>Respiratory System</strong></td>
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<td><strong>Oral Cavity</strong></td>
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Post-marketing Experience
Postmarketing experience indicates that more patients may develop allergic reactions, including anaphylaxis, following administration of terazosin controlled-release. There have been reports of priapism and breathe suppression during postmarketing surveillance. Atrial fibrillation has also been reported.

**Dosing and Administration**

- **Initial Dose:**
  - 1 mg as a bedtime is the starting dose for all patients, and this dose should not be exceeded. This initial dose should be strictly observed to minimize the potential for severe hypotensive effects.

- **Subsequent Doses:**
  - The dose may be slowly increased to achieve the desired blood pressure response. The usual recommended dose range is 1 mg to 5 mg administered once a day. However, some patients may benefit from doses as high as 20 mg per day. Doses over 20 mg do not appear to provide further blood pressure effect and doses over 40 mg have not been studied. Blood pressure should be monitored at the start of treatment, at 2 to 3 hours after dosing to see if the maximum and minimum responses are usual, and to evaluate symptoms such as dizziness or palpitations which can result from excessive blood pressure effect. Should overdosage of terazosin capsules lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished with volume expanders. If necessary, vasopressors should then be used and renal function should be monitored and monitored or needled. Laboratory data indicate that up to 10% of patients treated in clinical studies are shown to be metabolically abnormal, therefore, dialysis may be used if necessary.

**OVERDOSAGE**

- **Post-marketing Experience:**
  - Sympotamusic, Priapism, Hypertension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished with volume expanders. If necessary, vasopressors should then be used and renal function should be monitored and monitored or needled. Laboratory data indicate that up to 10% of patients treated in clinical studies are shown to be metabolically abnormal, therefore, dialysis may be used if necessary.

**DISCONTINUATION OF THERAPY:**

- **Use With Other Drugs:**
  - Caution should be observed when terazosin is administered concomitantly with other antihypertensive agents, especially the calcium channel blocker verapamil, to avoid the possibility of developing significant hypotension. When using terazosin capsules and other antihypertensive agents concomitantly, dosage reductions of either agent may be necessary (see PRECAUTIONS).

**Use In Pregnancy**

- **Use In Pregnancy:**
  - Terazosin capsules have been used in association with alpha-1 blocker therapy (see PRECAUTIONS).

**Dosage and Administration**

- **DOSAGE AND ADMINISTRATION:**
  - **Initial Dose:**
    - 1 mg as a bedtime is the starting dose for all patients, and this dose should not be exceeded as initial dose. Patients should be closely followed during initial administration in order to minimize the risk of severe hypotensive response.
  - **Subsequent Doses:**
    - The dose may be increased to a maximum of 1 mg in 1 mg increments daily. Doses of 10 mg once daily are generally required for the clinical response. Therefore, treatmen with 10 mg for a minimum of 1 to 6 weeks may be required to assess whether a beneficial response has been achieved. Some patients may not achieve a satisfactory response despite appropriate titration. Although some additional patients responded at a 20 mg daily dose, there was an insufficient number of patients studied to draw definitive conclusions about the effectiveness of 20 mg once daily.
  - **Post-marketing Experience:**
    - Sympotamusic, Priapism, Hypertension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished with volume expanders. If necessary, vasopressors should then be used and renal function should be monitored and monitored or needled. Laboratory data indicate that up to 10% of patients treated in clinical studies are shown to be metabolically abnormal, therefore, dialysis may be used if necessary.

**OVERDOSAGE**

- **Post-marketing Experience:**
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**DISCONTINUATION OF THERAPY:**

- **Use With Other Drugs:**
  - Caution should be observed when terazosin is administered concomitantly with other antihypertensive agents, especially the calcium channel blocker verapamil, to avoid the possibility of developing significant hypotension. When using terazosin capsules and other antihypertensive agents concomitantly, dosage reductions of either agent may be necessary (see PRECAUTIONS).

**Use In Pregnancy**

- **Use In Pregnancy:**
  - Terazosin capsules have been used in association with alpha-1 blocker therapy (see PRECAUTIONS).

**Dosage and Administration**

- **DOSAGE AND ADMINISTRATION:**
  - **Initial Dose:**
    - 1 mg as a bedtime is the starting dose for all patients, and this dose should not be exceeded as initial dose. Patients should be closely followed during initial administration in order to minimize the risk of severe hypotensive response.
  - **Subsequent Doses:**
    - The dose may be increased to a maximum of 1 mg in 1 mg increments daily. Doses of 10 mg once daily are generally required for the clinical response. Therefore, treatmen with 10 mg for a minimum of 1 to 6 weeks may be required to assess whether a beneficial response has been achieved. Some patients may not achieve a satisfactory response despite appropriate titration. Although some additional patients responded at a 20 mg daily dose, there was an insufficient number of patients studied to draw definitive conclusions about the effectiveness of 20 mg once daily.
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Terazosin Capsules Can Cause a Sudden Drop in Blood Pressure After the VERY FIRST DOSE. You may feel dizzy, faint, or “light-headed” particularly after you get up from bed or from a chair. This is more likely to occur after you’ve taken the first few doses, but can occur at any time while you are taking the drug. You should sit or lie down if you start feeling dizzy.

Other important facts about Terazosin Capsules for BPH

Terazosin Capsules help relieve the symptoms of BPH. It does NOT change the size of the prostate, which may continue to grow. However, a larger prostate does not necessarily cause more or worse symptoms.

Terazosin Capsules relax the tightness of a certain type of muscle in the prostate and at the opening of the bladder. This may increase the rate of urine flow and/or decrease the symptoms you are having.

Terazosin Capsules are not a treatment for prostate cancer. However, a man can have BPH and prostate cancer at the same time. Doctors usually recommend that all men be checked for prostate cancer once a year when they turn 50 (or 40 if a family member has had prostate cancer). These checks should continue even if you are taking Terazosin Capsules.

Your doctor has prescribed Terazosin Capsules for your BPH and not for prostate cancer. However, Terazosin Capsules do not affect PSA levels. You may want to ask your doctor if you should be checked for prostate cancer (see “Prostate Cancer Screening” below). You may want to ask your doctor if your PSA level should be checked more often than you were before taking Terazosin Capsules.

Treatment options for BPH

If Terazosin Capsules are helping you, you should notice an effect on your particular symptoms in 2 to 4 weeks of starting to take the medication. If Terazosin Capsules are helping you, you should notice an effect on your particular symptoms in 2 to 4 weeks of starting to take the medication.

Some men have an enlarged prostate gland, but no symptoms. Some patients may need surgery. Your doctor can describe several different surgical procedures to treat BPH. Which procedure is best depends on your symptoms and medical condition.

What Terazosin Capsules do to treat BPH

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• If Terazosin Capsules are helping you, you should notice an effect on your particular symptoms in 2 to 4 weeks of starting to take the medication.

• Even though you take Terazosin capsules, you may have Terazosin Capsules may not prevent the need for surgery in the future.

Other important facts about Terazosin Capsules for BPH

• You should use as much as you need to improve your symptoms in 2 to 6 weeks. So, you will need to continue seeing your doctor to check your progress regarding your blood pressure and to monitor your blood pressure in order to avoid any other regular checkups.

• Your doctor has prescribed Terazosin Capsules for your BPH and not for prostate cancer. However, men can have BPH and prostate cancer at the same time. Doctors usually recommend that men who have prostatic cancer also have a test for PSA. These tests should be done every year while you are taking Terazosin Capsules.

WARNINGS

Terazosin Capsules Can Cause a Sudden Drop in Blood Pressure After the VERY FIRST DOSE. You may feel dizzy, faint, or “light-headed” particularly after you get up from bed or from a chair. This is more likely to occur after you’ve taken the first few doses, but can occur at any time while you are taking the drug. You should sit or lie down if you start feeling dizzy.
Because of this effect, your doctor may have told you to take Terazosin Capsules as bedtime. If you take Terazosin Capsules as bedtime but need to get up frequently to go to the bathroom, go to the bathroom only as necessary. You should not drive or operate heavy machinery until you know how the medication affects you. It is also important to get up slowly from a chair or bed at any time and for a few hours after you have eaten the effects of the medication. If you get up too fast, you may feel dizzy or faint.

You will start with a 1 mg dose of Terazosin Capsules. Then the dose will be increased as necessary. Your health provider will tell you how many capsules to take each day.

Other side effects you could have while taking Terazosin Capsules include drowsiness, blurring or loss of vision, muscle weakness, or fainting. If you notice any unexpected effects you notice with your doctor.

Extremely rarely, Terazosin Capsules and similar medications have caused painful erection of the penis, sustained for hours and unrelieved by sexual intercourse or masturbation. This condition is serious, and if untreated, it can lead to permanent injury. If you have a prolonged erection, call your doctor or go to an emergency room or clinic immediately.

How to take Terazosin Capsules

Follow your doctor’s instructions about how to take Terazosin Capsules. You may need to take it every day at the same time. Talk with your doctor if you don’t take it for a few days, you may have to restart it 2 or 3 days later and continue dose as possible. Do not change Terazosin Capsules with anyone else, it was prescribed only for you.

Store Terazosin Capsules and all medicines out of the reach of children.

Sustained at 20°C (68°F) to 25°C (77°F) (see USP Controlled Room Temperature).

Protect from light and moisture.

FOR MORE INFORMATION ABOUT TERAZOSIN CAPSULES AND HYPERTENSION OR BPH, TALK WITH YOUR DOCTOR, NURSE, PHARMACY OR OTHER HEALTH CARE PROVIDER.

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Jubilant Cadista Pharmaceuticals Inc.

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**Product Information**

**Active Ingredient/Active Moiety**
- **Ingredient Name**: Terazosin Hydrochloride (UNII: D32S14F082)
- **Basis of Strength**: TERAZOSIN (UNII:8L5014XET7)
- **Strength**: 5 mg

**Inactive Ingredients**
- Gelatin (UNII: 2G86QN327L)
- Lactose Monohydrate (UNII: EWQ57Q8I5X)
- Magnesium Stearate (UNII: 70097M6I30)
- Sodium Lauryl Sulfate (UNII: 368GB5141J)
- Titanium Dioxide (UNII: 15FIX9V2JP)
- Starch, Corn (UNII: O8232NY3SJ)
- Silicon Dioxide (UNII: ETJ7Z6XBU4)
- D&C Yellow No. 10 (UNII: 35SW5USQ3G)
- D&C Red No. 28 (UNII: 767IP0Y5NH)
- FD&C Red No. 40 (UNII: WZB9127XOA)

**Product Characteristics**
- Color: orange (Bright Orange Opaque)
- Score: no score
- Shape: CAPSULE
- Size: 16mm
- Flavor:
- Imprint Code: TL385

**Packaging**
- Item Code (Source): NDC:70518-1875 (NDC:59746-385)
- Marketing Start Date: 02/14/2019
- Marketing End Date:
- Packaging: # 30 in 1 BLISTER PACK; Type 0: Not a Combination Product

**Marketing Information**
- Marketing Category: ANDA
- Application Number or Monograph Citation: ANDA075317
- Marketing Start Date: 02/14/2019

**Labeler**
- REMEDYREPACK INC.
- Phone: (829572556)

**Rev 2.1(2019) REMEDYREPACK INC.**