



1 IS THE CAT ADEQUATELY REGULATED ON ITS CURRENT TREATMENT?

YES

NO

2 VETERINARIAN/OWNER WANTS TO TRY VETSULIN[®]

3 SWITCHING A CAT FROM CURRENT TREATMENT TO VETSULIN[®]

- Discontinue the other treatment
- Start Vetsulin[®] (1 to 2 IU per cat twice daily) at the time the next dose would be due.

4 EVALUATE CAT 2-4 WEEKS AFTER STARTING VETSULIN[®]

Ask owner about changes in clinical signs and weigh cat



- Has the cat's water drinking increased, decreased, or stayed the same since your last visit?
- Has the frequency of your cat urinating changed since your last visit? Has the volume of urine passed changed?
- How is your cat's activity level? Does his/her activity seem normal? Or does he/she seem sluggish or too active?
- Has there been any significant change in weight? (Weight loss is usually suggestive of underdosing; weight gain is often suggestive of adequate dosing or overdosing.)

2 DETERMINE REASON FOR POOR GLYCEMIC CONTROL

- Associated with a human factor?**
- Is the treatment administered correctly? (recommend observing owner giving oral dose or injection in clinic)
 - Is someone new giving the treatment?
 - Is the correct syringe being used?
 - Is the insulin product prepared for use properly?
 - Is the correct dose being drawn into the syringe?
 - Is the injection site suitable?
 - Is diet appropriate for a diabetic cat?
 - Are treats being fed?
 - Does the cat eat other pets' food?
- Caused by treatment?**
- How long has the cat been on treatment? Is this long enough to see a response? (e.g., 2-4 weeks of insulin treatment)
 - Is the cat treatment dose appropriate?
 - Is the dosing interval appropriate?
- Caused by storage?**
- Is the insulin stored correctly?
 - Refrigerated at the correct temperature (i.e., not frozen)?
 - Stored upright?
 - Refrigerated between doses?
 - What is the expiration date of the insulin?
 - Is the insulin being diluted?
 - Has the insulin vial been used for longer than the identified usage period?
- Caused by concurrent disorder?**
- Inflammation (e.g., gingivitis, pancreatitis)
 - Infection (e.g., skin, urinary tract, periodontal disease)
 - Markedly overweight or obese
 - Renal insufficiency
 - Hyperthyroidism
 - Concurrent medication (e.g., corticosteroids, progestins)
 - Hypersomatotropism
 - Hyperadrenocorticism

Yes to any factor: Ensure you have identified any resolvable issues and rule out possible concurrent disorders that may be contributing to inadequate regulation before initiating treatment.
No to all factors: Begin treatment to reduce hyperglycemia and related clinical signs in diabetic cats.

3 SWITCHING AN INADEQUATELY REGULATED CAT FROM ANOTHER TREATMENT TO VETSULIN[®]

- Discontinue the other treatment
- Start Vetsulin[®] (1 to 2 IU per cat twice daily) at the time the next dose would be due.

5 USE A CONTINUOUS GLUCOSE MONITOR OR GENERATE SERIAL BLOOD GLUCOSE CURVE (SAMPLES TAKEN AT LEAST EVERY 2 HOURS)

Values that suggest hypoglycemia

- Nadir <120 mg/DL (6.7 mmol/L)

- If current dose is >2 IU twice daily and >1.5 IU/kg twice daily, go back to the recommended starting dose of 1-2 IU twice daily
 - If current dose is >2 IU twice daily and <1.5 IU/kg twice daily,
 - and the cat was poorly regulated clinically at its last check, go back to the recommended starting dose of 1-2 IU twice daily
 - and the cat was well regulated clinically at its last check, reduce the dose to the previous dose increment
 - If current dose is 2 IU twice daily, decrease to 1 IU twice daily
 - If current dose is 1 IU twice daily, skip the next insulin dose and reassess 12 hours later
- With any change in dose, re-evaluate in 2-4 weeks**

Values that suggest good regulation

- Majority of blood glucose curve values ranging between 120 and 300 mg/DL (6.7 and 16.7 mmol/L)
- Nadir between 120 and 200 mg/DL (6.7 and 11.1 mmol/L)
- Fructosamine <500 μmol/L

- Continue with current dose if clinical signs have improved
- If clinical signs have not improved, continue at current dose and recheck in 2-4 weeks

Values that suggest poor regulation

- Majority of blood glucose curve values >300 mg/DL (16.7 mmol/L)
- Nadir <120 mg/DL (6.7 mmol/L) or >200 mg/DL (11.1 mmol/L)
- Fructosamine >550 μmol/L

- ### 6 HAVE CLINICAL SIGNS (POLYURIA, POLYDIPSIA, WEIGHT LOSS) RESOLVED?
- Yes**
- Consider possibility of stress-induced hyperglycemia
 - Continue current dose and monitor fructosamine and weight every 1-3 months
 - Recheck blood glucose curve sooner if clinical signs (polyuria, polydipsia, weight loss, etc.) return and/or fructosamine is consistently high (>550 μmol/L)
- No**

Values that suggest Somogyi effect from insulin overdose

- Majority of blood glucose curve values >300 mg/DL (16.7 mmol/L)
- Nadir <120 mg/DL (6.7 mmol/L) (hypoglycemia followed by rebound hyperglycemia) or no discernible nadir (hyperglycemia can persist for a few days following hypoglycemia)

7 ARE CLINICAL SIGNS CONSISTENT WITH:

- Hypoglycemia**
- If the cat has gained weight since the last dose adjustment, suspect glycemic instability due to insulin overdose and decrease dose by 50% or go back to starting dose, whichever is lower
- Hyperglycemia**
- If the cat has lost weight since the last dose adjustment, increase the dose by 1 IU and recheck in 2-4 weeks

FEEDING PLAN:

- Feed *ad libitum* or two meals daily (provide food just prior to administering insulin)
- A diet suitable for a diabetic cat may encourage remission:
 - High protein, low carbohydrate (preferably canned)

GENERAL RECOMMENDATIONS:

1. Ideally, the blood glucose values will range between 120 and 300 mg/DL (6.7-16.7 mmol/L) for the majority of the curve in a well regulated diabetic cat.
2. The dose will most likely need to be adjusted until adequate regulation is achieved and may require future adjustments based on changes in weight or medical history.
3. Dose adjustments should be based on clinical signs and evaluation of continuous glucose monitoring or a serial blood glucose curve. Increases in dose should be made in 1 IU per injection increments (twice daily).
4. Allow at least 2-4 weeks between dose changes (unless evidence of hypoglycemia).
5. Educate the client on the need for and importance of using U-40 syringes with Vetsulin[®].
6. Discard open Vetsulin[®] after the stated in use shelf-life.

IMPORTANT SAFETY INFORMATION:

VETSULIN[®] and VETPEN[®] are for use in animals only. Dogs and cats known to have an allergy to pork or pork products should not be treated with VETSULIN[®]. VETSULIN[®] is contraindicated during periods of hypoglycemia. Animals with severe ketoacidosis, anorexia, lethargy, and/or vomiting should be stabilized with short-acting insulin and appropriate supportive therapy before use. As with all insulin products, careful patient monitoring for hypoglycemia and hyperglycemia is essential. Overdosage can result in profound hypoglycemia and death. Progestogen and glucocorticoid use should be avoided. The safety and effectiveness of VETSULIN[®] in puppies, kittens, breeding, pregnant, and lactating dogs and cats has not been evaluated. Keep out of reach of children. Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for at least 15 minutes. Accidental injection may cause clinical hypoglycemia. In case of accidental injection, seek medical attention immediately. Exposure to the product may induce a local or systemic allergic reaction in sensitized individuals. For complete safety information, refer to the product label.

Visit Vetsulin.com for more information

Vetsulin[®] (porcine insulin zinc suspension)

Approved by FDA under NADA # 141-236

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

vetsulin[®] is a sterile aqueous zinc suspension of purified porcine insulin.

Each mL contains:

Purified porcine insulin 40 IU

(35% amorphous and 65% crystalline)

Zinc (as chloride) 0.08 mg

Sodium acetate trihydrate 1.36 mg

Sodium chloride 7.0 mg

Methylparaben (preservative) 1.0 mg

pH is adjusted with hydrochloric acid and/or sodium hydroxide.

INDICATION

vetsulin[®] (porcine insulin zinc suspension) is indicated for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs and cats with diabetes mellitus.

DOSAGE AND ADMINISTRATION

FOR SUBCUTANEOUS INJECTION IN DOGS AND CATS ONLY

Vials: USE OF A SYRINGE OTHER THAN A U-40 SYRINGE WILL

RESULT IN INCORRECT DOSING. Shake the vial thoroughly until a homogeneous, uniformly milky suspension is obtained. Foam on the surface of the suspension formed during shaking should be allowed to disperse before the product is used and, if required, the product should be gently mixed to maintain a homogeneous, uniformly milky suspension before use. Clumps or white particles can form in insulin suspensions: do not use the product if visible clumps or white particles persist after shaking thoroughly.

Cartridges: VETSULIN[®] CARTRIDGES SHOULD BE USED EXCLUSIVELY WITH VETPEN[®] AND 29G/12 MM PEN NEEDLES. Prior to loading vetsulin[®] cartridges, shake the cartridge until a homogeneous, uniformly milky suspension is obtained. Clumps or white particles can form in insulin suspensions: do not use the product if visible clumps or white particles persist after shaking. The detailed instructions for use provided with VetPen[®] should be strictly followed. The injection should be administered subcutaneously, 2 to 5 cm (3/4 to 2 in) from the dorsal midline, varying from behind the scapulae to the mid-lumbar region and alternating sides. Always provide the Owner Information Sheet with each prescription.

Dogs

The initial recommended vetsulin[®] dose is 0.5 IU insulin/kg body weight. Initially, this dose should be given once daily concurrently with, or right after a meal. Twice daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice daily treatment is initiated, the two doses should each be 25% less than the once daily dose required to attain an acceptable nadir. For example, if a dog receiving 20 units of vetsulin[®] once daily has an acceptable nadir but inadequate duration of activity, the vetsulin[®] dose should be changed to 15 units twice daily. The veterinarian should re-evaluate the dog at appropriate intervals and adjust the dose based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Further adjustments in dosage may be necessary with changes in the dog's diet, body weight, or concomitant medication, or if the dog develops concurrent infection, inflammation, neoplasia, or an additional endocrine or other medical disorder.

Cats

The initial recommended dose in cats is 1 to 2 IU per injection. The injections should be given twice daily at approximately 12 hour intervals. For cats fed twice daily, the injections should be given concurrently with, or right after each meal. For cats fed ad libitum, no change in feeding schedule is needed. The veterinarian should re-evaluate the cat at appropriate intervals and adjust the dose based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Further adjustments in dosage may be necessary with changes in the cat's diet, body weight, or concomitant medication, or if the cat develops concurrent infection, inflammation, neoplasia, or an additional endocrine or other medical disorder.

CONTRAINDICATIONS

Dogs and cats known to have a systemic allergy to pork or pork products should not be treated with vetsulin[®]. vetsulin[®] is contraindicated during periods of hypoglycemia.

WARNINGS

User Safety: For use in animals only. Keep out of the reach of children. Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for 15 minutes. Accidental injection may cause clinical hypoglycemia. In case of accidental injection, seek medical attention immediately. Exposure to product may induce a local or systemic allergic reaction in sensitized individuals.

Animal Safety: Owners should be advised to observe for signs of hypoglycemia (see Owner Information Sheet). Use of this product, even at established doses, has been associated with hypoglycemia. An animal with signs of hypoglycemia should be treated immediately. Glucose should be given orally or intravenously as dictated by clinical signs. Insulin should be temporarily withheld and, subsequently, the dosage should be adjusted, if indicated. Any change in insulin should be made cautiously and only under a veterinarian's supervision. Changes in insulin strength, manufacturer, type, species (animal, human) or method of manufacture (rDNA versus animal-source insulin) may result in the need for a change in dosage. Appropriate diagnostic tests should be performed to rule out endocrinopathies in pets that are difficult to regulate (e.g., hyperadrenocorticism in dogs and hyperthyroidism in cats).

PRECAUTIONS

Animals presenting with severe ketoacidosis, anorexia, lethargy, and/or vomiting should be stabilized with short-acting insulin and appropriate supportive therapy until their condition is stabilized. As with all insulin products, careful patient monitoring for hypoglycemia and hyperglycemia are essential to attain and maintain adequate glycemic control and prevent associated complications. Overdosage can result in

profound hypoglycemia and death. Progestogens, certain endocrinopathies, and glucocorticoids can have an antagonistic effect on insulin activity. Intact bitches should be ovariectomized. Progestogen and glucocorticoid use should be avoided.

Drug Interactions:

In the US clinical effectiveness studies, dogs and cats received various medications while being treated with vetsulin[®] including antimicrobials, antivirals, antifungals, antihistamines, analgesics, anesthetics/tranquilizers, diuretics, bronchodilators, corticosteroids (cats), NSAIDs, thyroid hormone supplementation, hyperthyroid medication (methimazole), internal and external parasiticides, anti-emetics, dermatological topical treatments and oral supplements, ophthalmic preparations containing antimicrobials and anti-inflammatories, and various vaccines. No medication interactions were reported. This drug was not studied in dogs receiving corticosteroids.

Reproductive Safety:

The safety and effectiveness of vetsulin[®] in breeding, pregnant, and lactating dogs and cats has not been evaluated.

Use in puppies and kittens: The safety and effectiveness of vetsulin[®] in puppies and kittens has not been evaluated.

ADVERSE REACTIONS

Dogs

In the field effectiveness and safety study, 66 dogs were treated with vetsulin[®]. Sixty-two dogs were included in the assessment of safety. Hypoglycemia (defined as blood glucose < 50 mg/dL) with or without associated clinical signs occurred in 35.5% (22/62) of the dogs at various times during the study. Clinical signs of hypoglycemia were generally mild in nature (described as weakness, lethargy, stumbling, falling down, and/or depression). Disorientation and collapse were reported less frequently and occurred in 16.1% (10/62) of the dogs. Two dogs had a seizure and one dog died during the seizure. Although never confirmed, the presumptive diagnosis was hypoglycemia-induced seizures. In the rest of the dogs, hypoglycemia resolved with appropriate therapy and adjustments in insulin dosage. Seven owners recorded the following observations about the injection site on the home monitoring forms: swollen, painful, sore, and a bleb under the skin. The following clinical observations occurred in the field study following treatment with vetsulin[®] and may be directly attributed to the drug or may be secondary to the diabetic state or other underlying conditions in the dogs: hematuria, vomiting, diarrhea, pancreatitis, non-specific hepatopathy/pancreatitis, development of cataracts, and urinary tract infections. In a 21-day field safety and effectiveness study, 40 dogs, already well controlled on vetsulin[®], were administered vetsulin[®] using a VetPen[®] insulin pen loaded with a pre-filled 2.7 mL vetsulin[®] cartridge and 29 gauge/12 mm pen needles. All dogs enrolled in the study were evaluated for safety. Loss of diabetic control was reported in 10 dogs, 3 of which were withdrawn from the study. Four dogs' loss of control resolved after dose adjustment while still using the insulin pen. For the remaining 3 dogs, the loss of diabetic control was reported at the end of the study and outcome was not documented. Two dogs had injection site reactions: edema in one dog and two instances of crusting in another. Poor appetite and weight loss was reported in one dog.

Cats

In a field effectiveness and safety study, safety data was reported for 78 cats receiving vetsulin[®]. Hypoglycemia (defined as blood glucose < 50 mg/dL) was reported in 61 cats (88 total incidences). Fifteen of the occurrences (involving 13 cats) were associated with clinical signs described as lethargy, diarrhea, decreased appetite/anorexia, vomiting, and hypothermia. One cat had seizures following accidental overdosing by the owner and again during the subsequent dose adjustment period. The cat responded to supportive therapy and had no further hypoglycemic episodes. In all cases of hypoglycemia, the clinical signs resolved following symptomatic treatment and/or dose adjustment. Polyneuropathy was reported in 4 cats. Two injection site reactions were reported: one as a mildly thickened subcutaneous tissue reaction and the second as a mild bruising. The following clinical observations occurred in the field study following treatment with vetsulin[®] and may be directly attributed to the drug or may be secondary to the diabetic state or other underlying conditions in the cats: vomiting, lethargy, diarrhea, decreased appetite/anorexia, pancreatitis, dermal events, respiratory disease, urinary tract disorder, renal disease, dehydration, weight loss, polydipsia, polyuria, behavioral change, and ocular discharge/conjunctivitis. In a smaller field effectiveness and safety study, 14 cats were treated with vetsulin[®]. Hypoglycemia was reported in 6 cats (8 total occurrences). Lethargy not associated with hypoglycemia was reported in 4 cats (6 total occurrences). The following clinical observations occurred in the field study following treatment with vetsulin[®] and may be directly attributed to the drug or may be secondary to the diabetic state or other underlying conditions in the cats: foul odor to stool, diarrhea, dull coat, rapid, shallow breathing, stiff gait in rear, gallop rhythm, and pruritus with alopecia. During the 1998-2007 period, the following adverse events in 50 cats treated with porcine insulin zinc suspension were skin reaction, lethargy, vomiting/diarrhea, injection pain, hyperthermia, nystagmus, PU/PD, and abnormal behavior. In a 21-day field safety and effectiveness study, 36 cats, already well controlled on vetsulin[®], were administered vetsulin[®] using a VetPen[®] insulin pen loaded with a pre-filled 2.7 mL vetsulin[®] cartridge and 29 gauge/12 mm pen needles. Loss of diabetic control was reported in three cats all of which resolved after dose adjustment while still using the insulin pen. Hypoglycemia was reported in one cat. The cat recovered with supportive care and dose adjustment. To report suspected adverse drug experiences, call Merck at 1-800-224-5318.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

GENERAL PHARMACOLOGY

vetsulin[®] is a mixture of amorphous and crystalline insulin resulting in immediate and prolonged insulin activity. In dogs, vetsulin[®] may show two peaks of activity. In a laboratory study, 12 healthy adult Beagles were administered vetsulin[®] at a dose of activity varied from 10 to 24 hours. In

diabetic dogs, vetsulin[®] has two peaks of activity following subcutaneous administration (the first occurs at 2 to 6 hours and the second at 8 to 14 hours). The duration of activity varies between 14 and 24 hours. In cats, vetsulin[®] has a single peak of activity. In a laboratory study, 12 healthy adult cats were administered vetsulin[®] at a dose of 0.5 IU/kg. The onset of activity varied from 0.5 to 2 hours; the time to peak activity varied from 2 to 6 hours; and the duration of activity varied from 8 to 24 hours. In diabetic cats, the peak activity following subcutaneous administration of vetsulin[®] occurs between 1.5 and 8 hours, and the duration of activity varies between 8 and 12 hours. The peak(s) of activity, duration of activity, and dose required to adequately control diabetic signs vary between individuals and may vary in the same individual from day to day. The time ranges should only be considered as initial guidelines.

EFFECTIVENESS

Dogs

A total of 66 client-owned dogs were enrolled in and 53 completed the effectiveness and safety field study. The dogs completing the study included 22 breeds of purebred and various mixed breed dogs ranging in age from 4.8 to 14 years, and ranging in weight from 4.2 to 51.3 kg. Of the dogs completing the study, 25 were spayed females and 28 were male (21 neutered and 7 intact). Dogs were started on vetsulin[®] at a dose of 1 IU/kg plus a body weight-dependent dose supplement once daily. The initial treatment time to reach acceptable glycemic control (Dose determination period) ranged from 5 to 151 days. Dogs were evaluated for treatment effectiveness three times at 30-day intervals (Study Period). The blood glucose curve means and mean nadirs were compared pre- and post-treatment to assess effectiveness. Glycemic control was considered adequate if an acceptable blood glucose curve was achieved (reduction in hyperglycemia and a nadir of 60 - 160 mg/dL), clinical signs of hyperglycemia (polyuria, polydipsia, and ketonuria) were improved, and hypoglycemia (blood glucose < 50 mg/dL) was avoided. The blood glucose curve mean was reduced from 370 mg/dL pre-treatment to 151 mg/dL, 185 mg/dL, and 184 mg/dL at the three treatment period evaluations. The blood glucose mean nadir was reduced from 315 mg/dL pre-treatment to 93 mg/dL, 120 mg/dL, and 119 mg/dL at the three treatment period evaluations. Sixty days after an adequate vetsulin[®] dose was initially established, 94%, 96% and 83% of study dogs experienced a reduction in polyuria, polydipsia, and ketonuria, respectively. Investigators reported adequate glycemic control an average of 81% of the time during the Study Period. In a 21-day field safety and effectiveness study, 40 dogs, already well controlled on vetsulin[®], were administered vetsulin[®] using a VetPen[®] insulin pen loaded with a pre-filled 2.7 mL vetsulin[®] cartridge and 29 gauge/12 mm pen needles. Thirty-eight of 40 dogs were evaluated for effectiveness. Thirty-seven of the 38 owners (97.4%) said they were able to learn how to use the pen. Thirty-five of the 38 owners (92.1%) said the pen was well tolerated by the dogs. For 34 of the 38 dogs (89.5%), the investigators said that the diabetes was not negatively affected by the use of the pen.

Cats

A total of 85 client-owned cats (53 males and 25 females—all neutered) of various breeds were enrolled in a 60 day field effectiveness and safety study with continued use up to Day 180. Seven cats were removed from the study prior to the Day 7 evaluation. The remaining cats ranged in age from 3 to 17.5 years and in weight from 1.9 to 10.8 kg. Seventy-two cats completed the study to Day 60 and 66 cats completed to Day 180. The cats were started on vetsulin[®] at an initial dose of 1 to 2 IU insulin twice daily. Scheduled evaluations occurred at Days 7, 14, 30, 60, and 180. Dose adjustments were allowed at and between the evaluations. Effectiveness was based on blood glucose curve mean, blood glucose nadir and improvement in clinical signs. Blood glucose curve means decreased from 394 mg/dL on Day 0 to 217 mg/dL on Day 60. The mean blood glucose nadir decreased from 343 mg/dL on Day 0 to 146 mg/dL on Day 60. Fourteen client-owned cats (10 males and 4 females—all neutered) of various breeds were enrolled in a 60 day effectiveness and safety field study. The cats ranged in age from 5 to 14 years and in weight from 3.40 to 6.97 kg. Twelve cats completed the study. The cats were started on vetsulin[®] at an initial dose of 1 to 2 IU insulin twice daily. Scheduled evaluations occurred at Days 7, 14, 30, and 60. Dose adjustments were allowed at and between the evaluations. The blood glucose curve means decreased from 354 mg/dL on Day 0 to 162 mg/dL on Day 60. The mean blood glucose nadir decreased from 321 mg/dL on Day 0 to 99 mg/dL on Day 60. In a 21-day field safety and effectiveness study, 36 cats, already well controlled on vetsulin[®], were administered vetsulin[®] using a VetPen[®] insulin pen loaded with a pre-filled 2.7 mL vetsulin[®] cartridge and 29 gauge/12 mm pen needles. Thirty-six owners (100%) said they were able to learn how to use the pen. Thirty-four owners (94.4%) said the pen was well tolerated by the cats. For thirty-five cats (97.2%), the investigators said that the diabetes was not negatively affected by the use of the pen.

HOW SUPPLIED

vetsulin[®] is supplied as a sterile injectable suspension in multidose vials containing 10 mL of 40 IU/mL porcine insulin zinc suspension or in multidose cartridges containing 2.7 mL of 40 IU/mL porcine insulin zinc suspension. Vials are supplied in cartons of one, 10 mL vial. Cartridges are supplied in cartons of 10, 2.7 mL cartridges.

STORAGE CONDITIONS

Store in an upright position under refrigeration at 2°C to 8°C (36°F to 46°F). Do not freeze. Protect from light. The loaded VetPen[®] can be stored on its side.

Use contents within 42 days of first puncture.

Additional information about vetsulin[®], VetPen[®], and diabetes mellitus can be found at www.vetsulin.com Distributed by Intervet Inc. (d/b/a Merck Animal Health), Rahway, NJ 07065.

Formulated in Germany.

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